GETTING TO KNOW YOUR NEW NPN CHAIRS
Kristen Dominik, PharmD & P. Tim Rocafort, PharmD, BCACP

INAUGURAL HAITI HEALTH MISSION
An Academic-Community and Interprofessional Collaboration for Global Community Service and Lessons Beyond the Classroom

DEFINING LEADERSHIP
Most people would answer they know what leadership is when they see it, but to put it into words is a little more complicated.

CONTINUING EDUCATION
New guidelines for cholesterol management: What has changed?

Maryland Pharmacist

Med-Check Toolkit: Smart Medicine Management for Older Adults

As you may have heard, the Association is now the proud owner of a building in Columbia.This is a huge step for the future of the Association and we are very excited to be moving forward.

Dear Members,

There is a lot going on during our Board of Trustee meetings and we have already had a couple of late nights this year. Our August meeting was our Board Orientation so the existing and new board members would have a better understanding of the responsibilities required of them as board members. Our September meeting gave our committee chairs an opportunity to share their goals and action plan for their committees to finish up our last year on our Strategic Plan. As the year moves on, the Board will make plans to hold our next Strategic Planning session in the spring to position our Association to hit the ground running at Convention 2015.

As you may have heard, the Association is now the proud owner of a building in Columbia. We have formed the EFK Properties, LLC and that entity purchased 9115 Guilford Road. There are three tenants to the building including MPhA occupying one of the three spaces. Your MPhA board members have learned a lot more about mortgages, insurance policies, leases, inspections, and building plans than we ever thought we needed to know. They certainly did not teach this in pharmacy school! This is a huge step for the future of the Association and we are very excited to be moving forward. The building plans will be available to the membership and please be looking for announcements on how you can be a part of this exciting endeavor.

Our Selection Committee is working hard to find the right person for our Executive Director position. The candidates have been screened and initial interviews have been completed. There should be an announcement soon as to the new leader for our Association. We are excited for the possibilities that will come from having this important position filled.

These are big changes for the Association, however, we continue to take care of the regular business of realizing our mission. Our Association has also led the discussion process for developing the process required for community pharmacists to gain access to the full data available on the CRISP website. All pharmacists are currently available to register for access to the PDMP data available on CRISP. If you have not yet done so, please register at www.crisphealth.org. Many pharmacists use the available information on CRISP when dispensing controlled substance prescriptions. We are excited about the possibility of pharmacists having access to lab values and hospitalization records for the first time in a community setting. MPhA is working with the other state organizations to make this a reality.

October is American Pharmacists Month and MPhA is celebrating! We have a lot of activities planned and many will have already occurred by the time this letter goes out. We hope that you have had a chance to take advantage of some of the CE programming, community events, and even the Tweet-A-Thon! A big thank you to Nicole Culhane and her committee for coordinating the activities.

There is more information in Dixie's Interim Executive Director Message so I encourage you to read that as well. As you know, I have continued past my scheduled term as your President. I want to thank you for the opportunity that I have had in continuing to move our Association forward. As I transition to Chair of the Board, I look forward to serving you in a different position and look forward to seeing you at a meeting or event soon!

Sincerely,

Christine Lee-Wilson

Christine Lee-Wilson, PharmD
President

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A Quick Year in Review

The Maryland Pharmacists Association (MPhA) New Practitioner Network (NPN) has grown drastically in the past year through the leadership of Ashley Moody and Deanna Tran. Several of its members have actively participated in and developed events that cater to both new practitioners (NPs) and seasoned pharmacists alike to help support our organization and advance our profession. Keeping in mind its goal of providing a venue for new practitioners to exchange ideas and information to further professional development and grow their network, NPN has provided a valuable array of the following activities to uphold its mission:

- MPhA Mentorship Program – through collaboration between MPhA Professional Development and NPN committees
- "Striking Out with NPN" bowling night – event for new Maryland pharmacy residents and fellows
- "Coffee & Donuts with MPhA NPN with Class of 2015" – meet and greet event for upcoming graduates at all three Maryland pharmacy schools
- "Current Trends in Community, Geriatrics, and Ambulatory Care" – New Practitioner CE at the MPhA Mid-Year Meeting in Hyattsville, Maryland
- Happy Hours at various restaurants around Baltimore
- Graduation Celebration for the Class of 2014 – NPN hosted to celebrate new Maryland graduates from all three schools of pharmacy in Salisbury, Maryland

What's in Store for the Year Ahead?

Looking forward to the upcoming year, Kristen and Tim will be spearheading NPN to build upon its successes from the previous years and to expand its gamut of professional relations into new heights. In order to further the mission of this committee, they plan on completing the following objectives in addition to the aforementioned events:

- Dynamically engage the NPN committee with the other MPhA committees in order to ensure the voices of the NPs are heard, and collaboration with seasoned pharmacists is established and maintained
- Closely work with neighboring state pharmacy organizations who also have a NPN to expand connections and generate more novel ideas for practice and professional/personal development
- Proudly advocate for MPhA and its mission which would then increase membership and active involvement of its existing colleagues and newcomers

Truly, the future of our profession is in good hands with these highly motivated and innovative professionals. They continue to push the envelope forward while assuring that the advancement of the profession is their top priority.

GETTING TO KNOW YOUR NEW NPN CHAIRS

Kristen Dominik, PharmD

Kristen comes to the organization from Pittsburgh, Pennsylvania, where she will be cheering for her Pittsburgh Steelers and networking with all of *yinz* NPs with much hometown pride. She also is becoming an avid runner, having run a couple of half marathons recently. Kristen graduated in 2011 from Duquesne University and completed a PGY-1 community pharmacy residency with Walgreens and Massachusetts College of Pharmacy and Health Sciences. Currently, she works at United Healthcare as a Clinical Pharmacist, specializing in Medication Therapy Management.

P. Tim Rocafort, PharmD, BCACP

Tim comes to the organization from Lawrenceville, New Jersey, where he will be fist pumping for pharmacist provider status this year. At the same time, he enjoys a healthy dose of work-life balance which includes staying active outdoors and CrossFit. Tim graduated in 2010 from Rutgers University and completed a PGY-1 community pharmacy residency with Dominick's Pharmacy and University of Illinois at Chicago. Currently, he works at the University of Maryland School of Pharmacy as an Assistant Professor, specializing in Community Pharmacy Practice.

For further information on the New Practitioner Network or if you are interested in getting involved, please email Kristen or Tim at kristendominik13@gmail.com or ptimrocafort@gmail.com.

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Welcome to our *newest* members!

James Cianos
Ian Cook
Kenneth Ey
Ricardo Hernandez
Adrian Hui
Deepak Kapur
Farideh Kashani
Judy Lapinski
Patrick Maney
Briana Rider
Hank Sugarman
Nwanne Udeagha
Andrew Wherley
Eric Yospa

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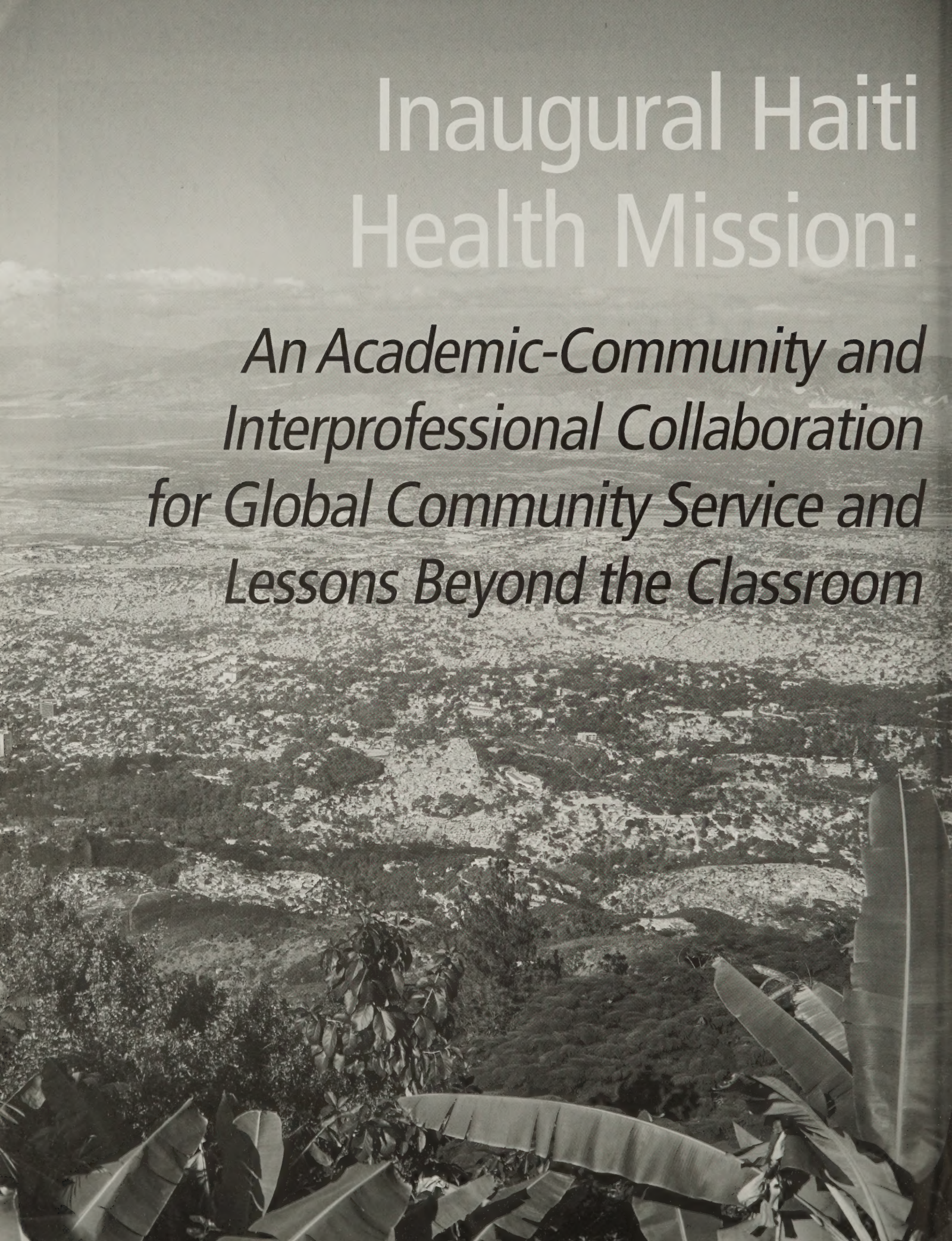
Stay Connected!
MarylandPharmacist.org

Inaugural Haiti Health Mission:

An Academic-Community and Interprofessional Collaboration for Global Community Service and Lessons Beyond the Classroom



Imagine traveling to an island in the Caribbean, seeing clear blue waters and palm tree-lined beaches, sensing the ocean breezes and waves and staying at a "top floor, waterfront condo" with meals being served three times a day. You may think, "Am I on a vacation or a mission?"

During the journey on the island, you may ride in an SUV on curvy, muddy, and unpaved terrain for hours, sometimes in the rain, across a river and in the night. Back at your condo, you may flip the switch but get no light, turn the faucet but get no water, and if you are lucky enough to take a shower, you become sweaty again minutes later. Better yet, you may enter the bathroom with a cockroach on the wall, wake up in the middle of the night with a chicken next to you, and obsessively apply DEET yet still attract hungry mosquitoes.

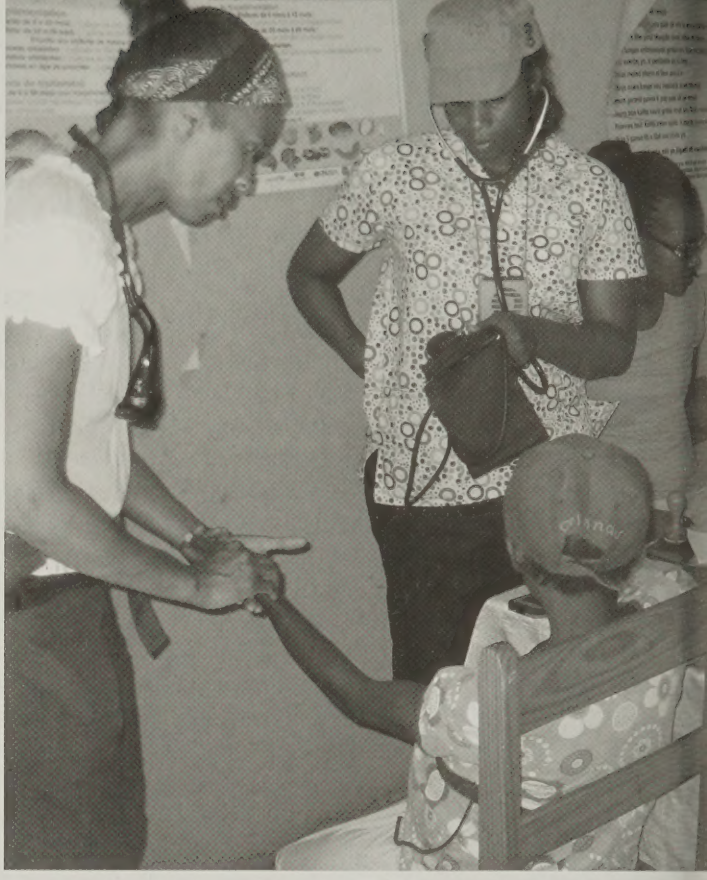
Does anyone want to join us for this vacation to the Caribbean? Only a few individuals were lucky enough to receive this real-world learning experience and life-changing opportunity. I ask you to reflect upon the beautiful land, yet consider the poor living conditions of the Haitian people. Commit to support it, go next time, or share with others about this mission to Haiti – the poorest country in the western hemisphere, perhaps the world.

On Thursday, May 29 at 6:00 a.m., thirteen people with a common purpose, often mentioned in health professional oaths to "aid in the relief in human suffering," departed the U.S. Capital for the Haitian Capital, Port-au-Prince. All left their loved ones, their luxury lifestyle, and their "e- and i-products" (e.g. iPad, iPhone, electronics, etc.) to embark on a journey to help the Haitian people on a weeklong mission trip.

This Haiti mission was an academic-community and interprofessional initiative among members of the University of Maryland Eastern Shore (UMES) School of Pharmacy and Health Professions (Pharmacy and Physician Assistant Programs), organizers from the Health and Education for Haiti, Inc. and St. Francis of Assisi Church, and pharmacist preceptor from the Indian Health Service, U.S. Public Health Service (USPHS). The interest and planning started about a year ago when Dr. Frank Nice, a retired captain from the USPHS and pharmacist at the U.S. Food and Drug Administration, came to speak to pharmacy and physician assistant students at a Professional Development Seminar. After the interest was piqued, he and his co-organizer, Mrs. Pat Labuda, came to UMES for multiple planning meetings. The Foreign Language Department at UMES provided pre-departures language and culture training to the team. Team members included:

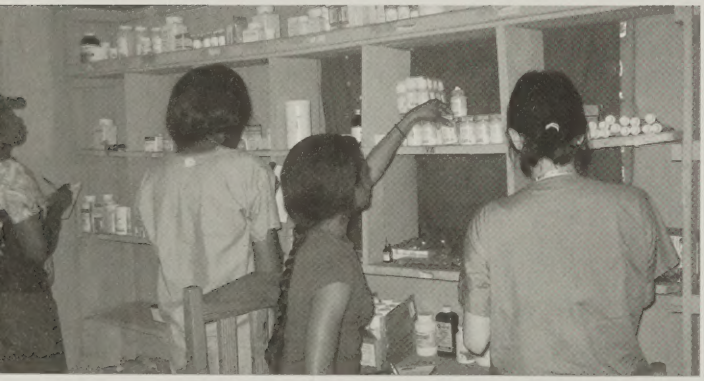
- Dr. Frank Nice, Health and Education for Haiti, Inc.
- Mrs. Pat Labuda, Health and Education for Haiti, Inc.
- Dr. Hoai-An Truong, UMES Pharmacy Faculty
- Dr. Yen H. Dang, UMES Pharmacy Faculty
- Ms. Annette Rogers, UMES Pharmacy Staff
- Dr. Jessica Steinert, USPHS Indian Health Service
- Dr. Courtney Murphy, UMES Pharmacy Alumna
- Ms. Maxine Cyprien, UMES Physician Assistant Student
- Ms. Melissa Graham, UMES Physician Assistant Student
- Ms. Renee Lindo, UMES Physician Assistant Student
- Ms. Kareemah Muhammed, UMES Pharmacy Student
- Ms. Adanna Anyiwo, UMES Pharmacy Student
- Ms. Kimberly Mitchell, UMES Pharmacy Student

Throughout the mission, the team conducted health needs assessments at two community clinics, set up two pharmacies, provided health care and medications for patients at a community clinic, toured two hospitals, visited an orphanage, and attended class at a nursing school. According to some team members, this mission is distinctive because



"See not just with your eyes, but with your heart. Care not just with your minds, but with your open hands."

— A reflection by Hoai-An Truong, PharmD, MPH



"we immerse ourselves – eat with the local hosts and live with the Haitian people." As volunteers we were kindly welcomed into the community where we were introduced to many people. Together, we worshipped in a church on the beach, taught in a primary school, participated in a talent show and dance, and walked along the beach with children. It was an amazing experience when the children held our hands when we walked and gave us conch shells as souvenirs, which will always remind us about the sounds of Haiti – the soul of the Caribbean.

The mission reinforced to us the true meaning of humanity and how all of us need the help and support of one another. I personally, experienced a touching moment as I encountered a man while walking along the path to the clinic. He spoke in Creole and I spoke in English. He walked up to me, shook my hand, and placed my hand over his heart on his bare chest. Humanity is the universal language. I understood. It was an indescribable feeling. I imagine that it would be hard for any team member to deny similar emotions at some point during the mission, especially when we personally interacted with our patients.

In addition to the humbling, rewarding experiences and amazing, lifelong memories, our lesson beyond the academic walls taught us new meanings to poverty, gratitude, flexibility, patience, emotion, attitude, and "chikungunya" – perhaps the most popular word due to a recent epidemic from mosquito bites. Fortunately, no one caught it and only one person felt sick for a couple days toward the end of the trip. Overall, the team supported each other and returned healthy.

On the first day of the mission, Dr. Nice stated, "we know that it will be and it is difficult as we experience life in a third world country. No matter how hard it may be, we come and go in a week. Yet, the Haitian people live there all their lives." Upon departure, team members wrote their actions to help Haitians or commit to support sustainability on a "postcard" which will be mailed to them 3 months post-trip. Let us always be reminded the lessons of simplicity, giving-back, or pay-it-forward as we return to our lives.

DEFINING Leadership

By: Dixie Leikach, RPh, MBA, FACA

Leadership is….

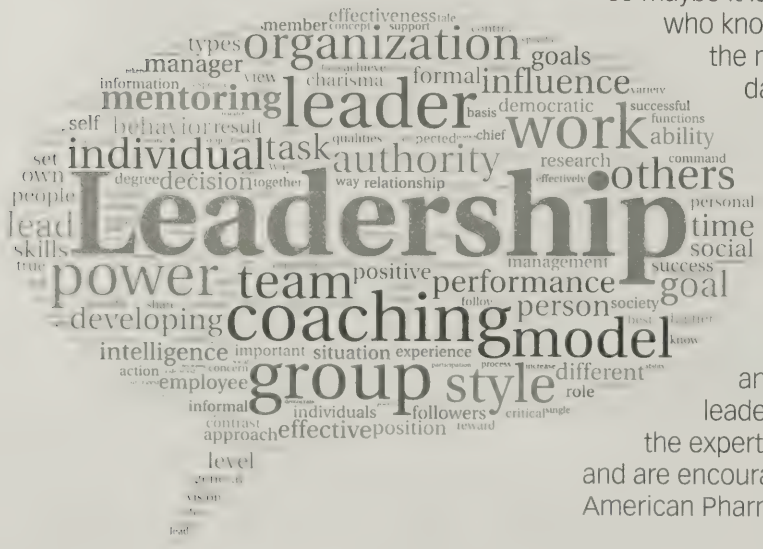
The sentence seems easy enough to define until asked the question. Most people would answer they know what leadership is when they see it, but to put it into words is a little more complicated.

As pharmacists tend to do, you start the research. Two styles of leadership, three styles of leadership, the five types of leaders, the 12 types of leaders, and on. The definition starts to get more complicated. The question starts to become whether there is a right answer, so more research is necessary. Move on to what is the best way to lead. Some argue that it is better to be a transformative leader instead of a transactional one. Transformative leaders are charismatic and focus on team building and goal setting. They look at the big picture and lead those on the team through personal growth. Transactional leaders are masters at getting the job done and keep everyone around them motivated by incentives and possibly fear. Different jobs need different leaders. A busy community pharmacy filling 500 prescriptions a day would probably wish for a transactional leader. A pharmacy association looking to grow might want a transformative leader. Most situations require a mixture of both. Research suggests that nurses will continue to perform well on the job despite the leadership style of the physicians with whom they work. This study shows that some professions intrinsically create leaders within that rise independently of their superiors on the job. The definition of the effect of leadership may change depending on the profession or situation.

Start to research publications on pharmacy leadership, as there must be answers to the question there. Pharmacy is a complicated profession so maybe it is best to go to those who know what it is like in the real world. It's a little daunting when those in your state who will potentially be reading this article wrote most of the books published on pharmacy leadership. New practitioners and those new to leadership benefit from the expertise in our profession and are encouraged to visit the American Pharmacists Association literature catalog for excellent references on the leadership topic.

There are many types of leadership, many "right" ways to lead, and many resources on the topic. The definition may be in whom we consider leaders. There may be a defining moment in when you are considered a leader, or it may be more gradual. The call to leadership is different for everyone. Some people find themselves in a position without any notice or training, and others may view it as a type of career path. The path to be a better leader is a continual one we should all strive to increase our education and experience to improve.

Trends and definitions may change, and the latest way to be a leader may have a different author. Yet, there are many things that will not change. At some point, you will be called to lead in your lifetime. It helps to be prepared for this. Membership and engagement with your state pharmacy association can provide opportunities for education and experience that will increase your knowledge base on the topic of leadership. The unique twist is that it will be applicable to your personal and professional life and you will get to experience it among your peers. This experience will include other pharmacists who are looking to increase their knowledge or are there to share their experiences. You have to show up to go up, so become a part of your profession and not just wait for it to come to you. That is what leaders do.



Member Mentions

On July 14, 2014, **Jeff Sherr**, owner of Apple Discount Drugs in Salisbury MD, has been awarded with the Health Mart Community Healthcare Excellence Award. This award was presented to Jeff for consistently providing care and services that add measurable value to patient health care and community wellness. The Health Mart Community Healthcare Excellence Award is a national pharmacy award that only 10 pharmacists across the country receive.

Dr. Cynthia Boyle, PharmD, FAPhA, MPhA Past President, has been named interim dean of University of Maryland Eastern Shores' (UMES) School of Pharmacy and Health Professions. Previously, Dr. Boyle has served as Professor and Chair of the Department of Pharmacy Practice and Administration at UMES since August 2011. She has practiced in community, institutions, and consultant settings and is an active member of the American Association of Colleges of Pharmacy, serving in multiple leadership roles and positions.

G. Lawrence Hogue, BS Pharm, PD, MPhA Speaker of the House, has been promoted to Assistant Dean for Professional Affairs at University of Maryland Eastern Shore School of Pharmacy and also remains as an assistant professor of Pharmacy Practice at UMES. His career path includes 8 years of experience in institutional pharmacy and 30 years of experience in independent community pharmacy practice.

Angelo C. Voxakis, PD, CEO of EPIC Pharmacies, Inc., will retire at the end of December after 16 years of service. Angelo has been an independent pharmacy owner since 1989 and has been President of EPIC Pharmacies, Inc. since 1999. EPIC was founded in 1982 and is a nationwide network of more than 1,000 independently-owned pharmacies. Angelo graduated from the University of Maryland School of Pharmacy in 1971.

Nicole Brandt, PharmD, BCPP, CGP, FASCP, Associate Professor at the University of Maryland School of Pharmacy, was elected the 2014-2015 American Society of Consultant Pharmacists (ASCP) President-Elect. Nicole graduated from the University of Maryland School of Pharmacy in 1997 and completed a geriatric residency and is board certified in psychiatric and geriatric pharmacy. Nicole has been actively involved in ASCP since 2002.

Magaly Rodriguez de Bittner, PharmD, BCPS, CDE, FAPhA, professor and chair of the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy was named a Maryland *Daily Record* 2014 Innovator of the Year. The *Daily Record* is a leading business and legal news publication and recognizes Marylanders for their innovative spirit. Dr. Rodriguez de Bittner was selected for her efforts to establish and expand the Maryland P3 Program across the nation.

Do you have good news to share?

Send your Member Mention to kelly.fisher@mdpha.com.

Please enclose a photo if possible.

Med-Check Toolkit:

Smart Medicine Management for Older Adults

By Jennifer Thomas, PharmD

Medication reconciliation is the process of documenting a patient's complete, accurate medication list at times of transitions in care and comparing the list to prior lists to ensure changes are addressed. The medication reconciliation process is recognized as critical for patient safety and is most often discussed in the context of the hospital setting, during admission, transfer and discharge. However, medication reconciliation is equally important in other care settings (nursing homes, hospice, ambulatory care, outpatient settings, other) especially at patient transitions between these different care settings.[1]

In one study investigating medication discrepancies conducted in an academic hospital, over one-third (35.9%) of patients had medication errors on admission and 85% of these were errors in medication histories. The authors suggested that prescribers and other clinicians should help patients obtain and maintain a complete, accurate and understandable medication list.[2]

Recognition of the need to engage patients and their family and care givers in medication reconciliation was recently the focus of a collaborative project by the three pharmacy schools in Maryland and the Delmarva Foundation, National Disparities Coordinating Center. The teams included: Dr. Chanel Agness, Dr. Leah Sera, Roxanne Zaghab, Dr. Regina Atim, and Peter Barakat, PharmD Candidate, from the University of Maryland; Dr. Regine Beliard, Dr. Jennifer Bailey, Dr. Ashley Wensil and Dr. Min Kwon from Notre Dame of Maryland University; and Dr. Hoai-An Truong, Dr. Lana Saad and Rosemary Botchway from the University of Maryland Eastern Shore. The primary aim of the team collaborative was the development of a medication safety toolkit to include a medication reconciliation process applicable to patients and caregivers. A secondary aim was to develop training videos and slide sets for patient care advocates, such as community health workers and healthcare professions students, to educate patients, their families and caregivers about the importance of having knowledge of their medications.

While there are a number of medication reconciliation tools with the focus of healthcare professionals to complete the medication list, there is a paucity of tools that focus on education of patients and/or patient health advocates to complete medication reconciliation. Two key elements were identified early in the development of the toolkit by the collaborative team as key to successful medication reconciliation:

Understanding the importance of maintaining a current list of medications at all times

Maintaining a current list of medications is the foundation for education to the patient on medication management. However, having a current list of medications, available at all times, is difficult, especially for those patients that have multiple medications, multiple prescribers, multiple

pharmacies, low health literacy (the majority of patients), and other factors such as reading and/or vision limitations. The collaborative team created the Med-Check Passport which is a document analogous to the country of residence Passport. Just as the traveler must carry their citizen passport to visit another country, the patient must carry their "Med-Check Passport" medication list when they visit their healthcare prescribers and pharmacies.

Understanding that medication changes are significant

The Med-Check Passport emphasizes the medication changes that occur within the patient's medication list and provides a specific column within the table to document the reason for the change.

Examples of the Med-Check Passport

Version 1: Used by community health workers and patients; developed by Notre Dame of Maryland University and University of Maryland. Show your Med-Check Passport at every medical appointment.

See Med-Check Passport: http://youtu.be/1LQC9Fo3EAw

Med-Check Questions

Questions the community health worker can ask the patient

If the patient answers **YES** to **ANY** question, tell the patient to tell their pharmacist or doctor!

1. Do you use more than one pharmacy?
2. Do you have trouble paying for your medications?
3. For each medication you listed, are there any sections in the green or blue column that you could not fill out?
4. Have you stopped taking any of your medications on your own without telling your doctor?
5. Do you have trouble remembering to take any of your medications?

Directions

Step 1
Fill out the **first 6 columns** with **all** medications you are supposed to take

Step 2
Fill out the **last 3 columns** every time there is a change to your medications

Step 3
Fill out the **first 6 columns** every time you start a new medication

Remember
Include all prescription medications, over the counter medications, vitamins, minerals and special teas.

Completed by: _____

MED-CHECK PASSPORT

Start Date	Medication	What I Take It For	Dose	When I Take It	I Have Trouble Taking It*	Changes	Reason for Change	Change Date

*No = N

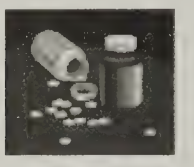
*Yes. Reasons = transportation (T), cost (C), told by family or friend to not take medication (M), side effects (S), forgets (F), I take it differently than prescribed (P), I don't think I need this medication (D)

Version 2: Used by student pharmacists and patients; developed by University of Maryland Eastern Shore.
See How to use the Med-Check Passport:
https://www.youtube.com/watch?v=sVXaL1DORe0&list=UUVGUqYdfhULoalbP7cMOKwg

Med-Check Passport

Bring it to every doctor or pharmacy visit

You will write down a list of all the medications that you are taking, how you take them, how much, and how often.
(Include the medications you buy over-the-counter, herbals, vitamins, supplements, etc.)



We will review them to properly take care of you.

Talk to your doctor or pharmacist if you have any questions about your medications

Name:_____

Telephone number:_____

Pharmacy:_____

Doctor:_____

Do you have any allergies (list all)?

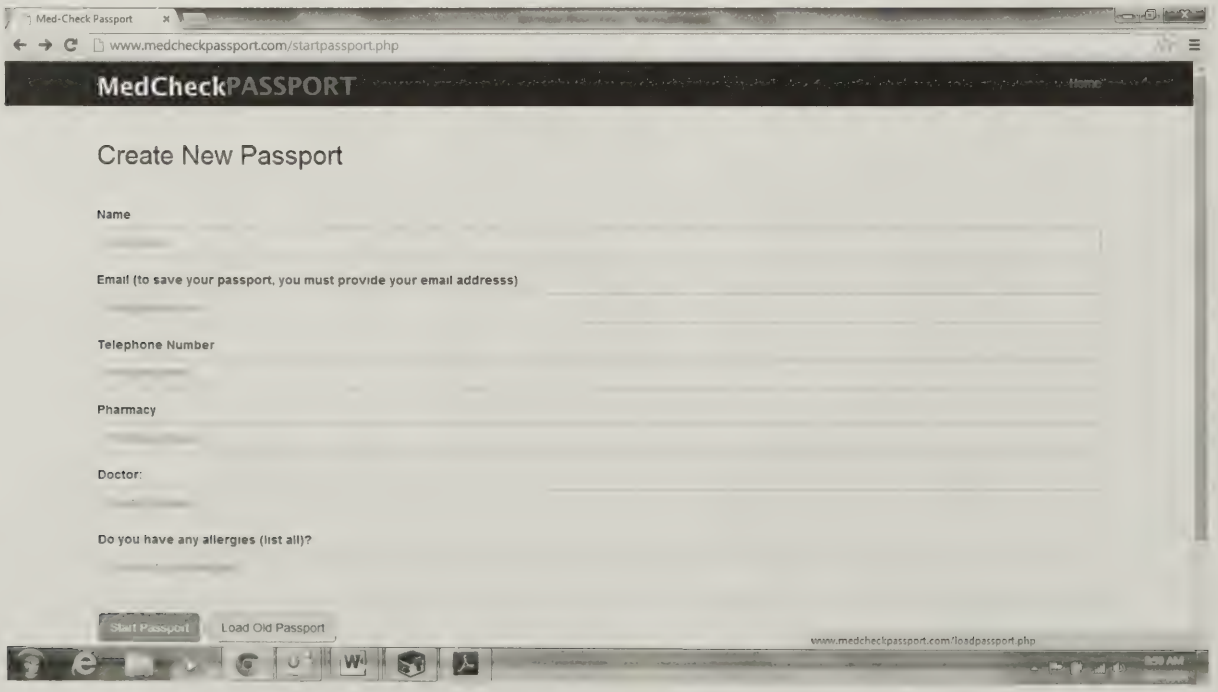
_____

_____

Quality Improvement Organizations | DNCC | DFMC

Developed in partnership by the University of Maryland Eastern Shore (UMES) School of Pharmacy, and the Primary Care Coalition of Montgomery County. This material was prepared by the Delmarva Foundation for Medical Care (DFMC), the Disparities National Coordinating Center, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. 10SOW-MD-DNCC-071114-558

Example of the electronic Med-Check Passport: www.medcheckpassport.com



Example Disease State Module: Heart Failure MedCheck Symptoms Check

This tool can help you keep track of heart failure symptoms. Use this tool to understand what to do if your heart failure symptoms get worse.

The toolkit is a package of educational materials with training videos, paper tools, and an electronic application to specifically assist patients and non-professionals that work with patients to obtain and maintain their medication list. Specific toolkit components include: the Med-Check Passport, medication list (2 versions) and associated video instructions; the Smart Medicine Safety Checklist with video, a screening tool to identify potential medication problems; and the Heart Failure Symptoms Check with instructional videos, a tool to provide a disease state specific medication and symptoms review, along with suggested actions for the patient to take. The complete Med-Check Toolkit may be accessed at the Delmarva Foundation website.[3] (Note: The toolkit may also be posted on the Maryland Pharmacists Association website and on the individual School of Pharmacy web resources.)

As American Pharmacists Month is fast approaching there is an opportunity for pharmacists and other healthcare professionals to avail themselves of the Med-Check Toolkit as valuable resources to engage with their patients to improve medication reconciliation. To obtain the most value from the Med-Check Toolkit the reader may wish to review all the paper tools and videos[3].

Chart 1 - Heart Failure MedCheck – Symptoms Check

Patient name: _____

SYMPTOMS	GREEN ZONE	ACTION
• No shortness of breath • No increase in swelling • No weight change • Normal activity	GO	• Continue taking medication as directed
SYMPTOMS	**YELLOW ZONE**	**ACTION**
• Increased shortness of breath • Increased swelling • Weight change by 2 pounds in a day • Weight change by 5 pounds in a week • Decreased activity	CAUTION	• Call your doctor
SYMPTOMS	**RED ZONE**	**ACTION**
• Symptoms in the yellow zone are not better after calling your doctor • Shortness of breath that won't go away • Chest pain that won't go away • Dizziness or fainting	DANGER	• Get help from the doctor now OR • Call 9-1-1 for help

Chart 2 - Heart Failure MedCheck – Symptoms Check

Patient name: _____

Check for the following symptoms daily and write in your zone color:

GREEN GO YELLOW CAUTION RED DANGER

DATE	MONDAY 4/4/2014	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
BREATHING 	GREEN	GREEN					
SWELLING 	GREEN	YELLOW					
WEIGHT 	GREEN 160LBS	YELLOW 162LBS	_____LBS	_____LBS	_____LBS	_____LBS	_____LBS
ACTIVITY LEVEL 	GREEN	YELLOW					
ACTION	CONTINUE	CALL DOCTOR					

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Medication Safety http://www.dcqio.org/providers/pharmacymedication-safety/medication-safety

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New guidelines for cholesterol management: What has changed?

Cholesterol and triglycerides are the major lipids circulating in the human body. They are transported as complexes of lipids and proteins known as lipoproteins. The three major classes of lipoproteins are low-density lipoproteins (LDL), high-density lipoproteins (HDL), and very-low-density lipoproteins (VLDL). Hyperlipidemia is a group of disorders characterized by an excess of serum cholesterol, especially low-density lipoproteins and/or excess triglycerides. It is classified as either primary hyperlipidemia (genetic or familial) or secondary hyperlipidemia which can be caused by age, diabetes mellitus, hypothyroidism, Cushing's syndrome, chronic kidney disease, or cholestatic disorders. Several drug classes have been linked to secondary hyperlipidemia, including: HIV protease inhibitors, atypical antipsychotics, corticosteroids, isotretinoin, beta-blockers, thiazide diuretics, azole antifungals, cyclosporine, tacrolimus and some types of oral contraceptives.[1] Several studies have established a definitive association between elevated levels of LDL cholesterol and the risk of cardiovascular disease.[1]

Learning Objectives: After reading this article, the learner will be able to:

1. Identify the 5 main differences between the 2013 ACC/AHA lipid guidelines and 2002 Adult Treatment Panel-III guidelines.
2. Recognize the four patient population groups that would benefit from HMG CoA reductase inhibitor (statin) therapy based on the new ACC/AHA treatment guidelines.
3. Recommend a statin therapy based on a patient's risk level.

Key Words: Hyperlipidemia, statins, cholesterol, LDL, ATP III, HMG CoA reductase inhibitors

In 1988, the National Heart, Lung, and Blood Institute (NHLBI) began publishing the National Cholesterol Education Program - Adult Treatment Panel (NCEP-ATP) guidelines for hyperlipidemia management. Since its inception ATP-I has been updated once in 1993 (ATP-II) and again in 2002 (ATP-III).[1,2] However, in response to the 2011 Institute of Medicine's report on the development of trustworthy guidelines, the NHLBI Advisory Council recommended that the NHLBI focus specifically on reviewing the highest-quality evidence and partner with other organizations.[2-4] Accordingly, in June 2013 the NHLBI initiated collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA) to complete and publish these guidelines.

The 2013 ACC/AHA lipid guidelines provide a new approach to the treatment of hyperlipidemia, which deviates from the ATP-III guidelines in a number of ways.[5] The purpose of this article is to highlight the key differences between the current and

previous guidelines. These differences include treatment population, goals of therapy, selection of lipid lowering medications, a new risk calculator and safety and monitoring of regimen.

Identification of Treatment Population

The first difference is the patient population that is likely to benefit from statin therapy. The 2013 ACC/AHA lipid guidelines identify four groups whom are likely to benefit from statin therapy. These four patient groups include the following (see Table 1):

- History of arteriosclerotic cardiovascular disease (ASCVD)
- LDL-cholesterol > 190 mg/dl
- Between 40 and 75 years of age with a history of diabetes
- Between 40 and 75 years of age and a 10-year ASCVD Risk > 7.5%

Therapeutic Goals

The second key difference is the goals of hyperlipidemia therapy (Table 2). In previous guidelines, therapy was targeted towards a specific LDL and non-HDL goal based on the presence of comorbidities. However, the advisory panel for the ACC/AHA recommended that the goal of therapy should be cardiovascular event reduction. The best way to accomplish this is for patients identified as statin eligible, as stated in table 2, to be on the maximum tolerated statin intensity regardless of their LDL level. The guidelines discuss specifically using high and moderate intensity statins to accomplish this goal. More information about statin intensity will be provided later in the article.

Selection of Lipid-lowering medications

In the ATP-III guidelines, selection of the lipid lowering agent depended on several factors. The first consideration was the patient's lipoprotein profile and whether there were additional lipid abnormalities beyond an elevated LDL. Second, the magnitude of change needed to reach the goal of therapy was considered. Finally, concomitant drug therapies that may increase the risk of side effects and/or the presence of other medical disorders that may influence drug metabolism were considered.[2] Statins are usually the drug of choice due to their effectiveness in lowering LDL and tolerability by most patients. However, the ATP-III guidelines gave prescribers the option to initiate patients on alternative lipid-lowering agents (Table 3). If the patient did not have an adequate response, prescribers then could either change therapy to a statin or use the statin in combination with a non-statin to achieve target LDL goals.

On the other hand, the new ACC/AHA guidelines focus on optimizing statin based therapy for cardiovascular event risk reduction. The new guidelines classify statins based on their lipid lowering intensity (Table 4). Patients receive either moderate- or high-dose statin therapy depending on which of one of the four "statin benefit groups" they fit into. High-intensity options lower the LDL by approximately 50% and include: 20 or 40 mg of rosuvastatin daily or 40 or 80 mg of atorvastatin daily. Patients who should receive a high-intensity statin include the following: patients with clinical ASCVD, LDL >190, and patients with diabetes AND estimated 10-year ASCVD risk ≥7.5%. In general it is recommended that patient start on the highest dose and titrate down if they develop adverse events. According to the new guidelines, moderate-intensity therapy is acceptable for

Table 1: Methods and Outcomes

ATP-III[1]	2013 ACC/AHA[4]

• Coronary heart Disease patients (CDH)
  • Acute Coronary Syndrome
  • Myocardial Infarction
  • Stable or unstable angina
  • Revascularization procedures
  • Coronary angiography
  • Coronary artery surgery
  • Other atherosclerotic diseases
  • Peripheral vascular Disease
  • Abdominal aortic aneurysm
  • Carotid artery disease
• CHD risk equivalent
  • Diabetes mellitus (type I or II)
  • 2+ risk factors
  • Cigarette smoking
  • Hypertension (BP ≥140/90 mmHg or on antihypertensive medication)
  • Low HDL cholesterol (<40 mg/dL)
  • Family history of premature CHD (CHD in male first-degree relative <55 years; CHD in female first-degree relative <65 years)
• 20% Calculated 10 year CHD Risk
	• Clinical Atherosclerotic Cardiovascular Disease (ASCVD)
	  • Acute Coronary Syndrome
	  • Myocardial Infarction
	  • Stable or Unstable Angina
	  • Revascularization Procedures
	  • Stroke or Transient Ischemic Attack
	  • Peripheral Arterial Disease Atherosclerotic in Origin
	• LDL > 190 mg/dL
	• Diabetes mellitus (type I or II) AND Age 40-75 years
	• 10-year ASCVD Risk > 7.5% AND Age 40-75 years

patients who are 40 - 75 years of age with diabetes AND have an estimated 10-year ASCVD risk <7.5%, patients with an LDL of 70 mg/dL - 189 mg/dL, patients who have no evidence of clinical ASCVD, and patients with a 10-year risk of ASCVD that is less than 7.5% or patients who are 75 years of age or older with ASCVD.

Another major change in the new hyperlipidemia guideline is the downgrading of non-statin treatment options. Per the ACC/AHA expert panel, "Non-statin therapies do not provide acceptable ASCVD risk reduction benefits compared to their potential for adverse effects in the routine prevention of ASCVD".[5] This recommendation is anticipated to eventually lead to a reduction in the number of prescriptions for ezetimibe, ezetimibe-containing products, bile acid sequestrants, fibrates, niacin, niacin-containing products and omega-3 fatty acids.[5]

New Risk Calculator

The ACC/AHA guidelines now utilize a pooled cohort risk assessment instead of the Framingham Risk Calculator, to estimate 10-year and lifetime risks for a patient to develop ASCVD (defined as coronary death or nonfatal myocardial infarction, or fatal or nonfatal stroke). The information required to estimate ASCVD risk includes age, sex, race, total cholesterol, HDL cholesterol, systolic blood pressure, blood pressure lowering medication use, diabetes status, and smoking status. This tool is available through www.my.americanheart.org either as a mobile application or a web-based calculator.[6]

As a result of new recommendations in the 2013 ACC/AHA hyperlipidemia guidelines, the number of adults receiving statin therapy in the United Sates is expected to increase from 43.2 million to 56.0 million. Most of this increase (10.4 million of 12.8 million) would occur among adults without a history of cardiovascular disease. Among adults between the ages of 60 and 75 years without cardiovascular disease who are not receiving statin therapy, the percentage of those who would be eligible for such treatment would increase from 30.4% to 87.4% among men and from 21.2% to 53.6% among women.[7,8]

Statin Safety & Monitoring

Another difference between the guidelines is the recommendations for monitoring statin therapy. Both guidelines agree that the following items should be assessed regularly: adherence to medication and lifestyle modifications, therapeutic response to statin therapy, and safety. Refer to Table 5 for a comparison of recommended monitoring.

Liver Function Tests

The 2013 ACC/AHA guidelines recommend against routine monitoring of liver function tests (LFTs) but recommend that baseline LFTs be obtained in all patients prior to statin therapy initiation. The guidelines state that based on recent randomized clinical trials the incidence of transaminitis in individuals on high-dose statin therapy is less than 1.5% over 5 years.

Table 2: Goals of hyperlipidemia therapy	
ATP-III[1]	**2013 ACC/AHA[4]**
Treatment LDL goals based on lipid serum levels and risk stratification • CHD and CHD Risk Equivalent <100 mg/dL • Framingham 10 year risk >20% <100 mg/dL • Multiple (2+) Risk Factorsa <130 mg/dL • 0–1 Risk Factor <160 mg/dL	• Cardiovascular events risk reduction • Treating to a target LDL goal is not recommended • Use maximum tolerated statin intensive therapy
a Heavy smoker, uncontrolled hypertension, strong family history of premature CHD, or very low HDL cholesterol	

Elevation in LFTs associated with low- or moderate-intensity statin therapy occurred at rates similar to those seen with placebo or no statin treatment controls.

Creatinine Kinase

The 2013 ACC/AHA guidelines recommend against routine CK monitoring. In contrast to the ATP-III guidelines, which recommend evaluation of CK levels prior to therapy initiation and again if a patient presents with symptoms of muscle pain, the new guidelines recommend evaluating CK initially only if the patient is at high risk for developing adverse muscle events. These include patients with personal or family history of statin intolerance or muscle disease, have clinical signs and symptoms of muscle disease, or are on concomitant drug therapy that might increase the risk for myopathy. Some examples of medications which can increase the risk for myopathy include fibrates such as gemfibrozil and niacin. The guidelines provide an algorithm to avoid unnecessary discontinuation of statin therapy due to muscle pain complains (Figure 1).[5]

Diabetes

There is moderate evidence that patients on statin therapy are at risk of developing new onset of diabetes mellitus (Number needed to harm [NNH] = 100 in primary prevention and 500-1000 in secondary prevention).[9] The new guidelines recommend that patients who develop diabetes while on statin therapy should adhere to a heart healthy diet, engage in physical activity, achieve and maintain a healthy body weight, cease tobacco use and to continue statin therapy.

Triglycerides (TG)

The ACC/AHA could not find evidence that starting triglyceride-lowering medication therapy for TG levels of 500-1000 mg/dL lowered the risk of hyperlipidemic pancreatitis. The guidelines recommend evaluating and addressing secondary causes of elevated TG levels and implementing diet and lifestyle modifications as first line therapy for these patients rather than starting them on triglyceride lowering medication. The ACC/AHA guidelines now recommend that therapies targeted at TG be initiated when the value is > 1000 mg/dl. Table 6 compares the triglyceride management recommendations for each of the guidelines.

Table 3: Recommended lipid-lowering agents	
ATP-III[1]	**2013 ACC/AHA[5]**

• HMG CoA reductase inhibitors (statins)
  • Atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin & simvastatin
• Bile acid sequestrants
  • Cholestyramine, colestipol & colesevelam
• Nicotinic acid derivatives
  • Niacin extended release
• Fibric acid derivatives (fibrates)
  • Gemfibrozil, fenofibrate
• Antilipemic Agent
  • Ezetimibe
• Omega-3 fatty acids
	• HMG CoA reductase inhibitors (statins)
	  • Atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin & simvastatin
	• Adjunct therapy (statin + nonstatin) is not recommended due to lack of supporting evidence

Table 4: ACC/AHA statin classification[5]		
A High-Intensity Statin Therapy	**Moderate-Intensity Statin Therapy**	**Low-Intensity Statin Therapy**
Daily dose lowers LDL by approximately ≥50%	Daily dose lowers LDL by approximately 30% to <50%	Daily dose lowers LDL by <30%
Atorvastatin (40)–80 mg QD Rosuvastatin 20 (40) mg QD	Atorvastatin 10 (20) mg QD Rosuvastatin (5) 10 mg QD Simvastatin 20–40 mg QD Pravastatin 40 (80) mg QD Lovastatin 40 mg QD Fluvastatin XL 80 mg QD Fluvastatin 40 mg BID Pitavastatin 2–4 mg QD	Simvastatin 10 mg QD Pravastatin 10–20 mg QD Lovastatin 20 mg Fluvastatin 20–40 mg BID Pitavastatin 1 mg QD

Table 5: Statin monitoring		
	ATP-III[1]	**2013 ACC/AHA[5]**
Fasting Lipid panel	Evaluate initially, approximately 4-12 weeks after starting, then annually or more frequently if indicated.	Evaluate initially, approximately 4-12 weeks after starting, then annually or more frequently if indicated.
Liver function test (AST & ALT)	Evaluate initially, approximately 12 weeks after starting, then annually or more frequently if indicated.	Evaluate initially, and then only if patient is developing symptoms suggesting hepatotoxicity.
Muscle soreness, tenderness or pain Creatinine Kinase (CK)	• Evaluate muscle symptoms and CK initially. • Evaluate muscle symptoms at each follow-up visit. • Obtain a CK when persons have muscle soreness, tenderness, or pain.	• Evaluate CK initially if patient believed to be at increased risk for adverse muscle events. • CK should not be routinely measured in individuals receiving statin therapy. • If patient present with muscle weakness follow the algorithm (Figure 1).

Table 6: Triglyceride management	
ATP-III[1]	**2013 ACC/AHA[5]**

Borderline High Triglycerides (150–199 mg/dL):
• Implement diet and lifestyle modifications
  • Body weight control
  • Regular physical activity
  • Smoking cessation
  • Restriction of alcohol use
  • Avoid high carbohydrate intakes (>60% of calories)
	Borderline High Triglycerides (150–999 mg/dL):
	• Implement diet and lifestyle modifications
	  • Body weight control
	  • Regular physical activity
	  • Smoking cessation
	  • Restriction of alcohol use
	  • Avoid high carbohydrate intakes (>60% of calories)

High Triglycerides (200–499 mg/dL): • First line: Implement diet and lifestyle modifications • Second line: Use Statin/Niacin/Fibrates	
Very High Triglycerides (≥500 mg/dL) • First line: Triglyceride-lowering drugs (fibrate or nicotinic acid) • Second line: Implement diet and lifestyle modifications	Very High Triglycerides (≥1000 mg/dL) • Add Triglyceride-lowering drugs (fibrate or nicotinic acid) in addition to statin • Implement diet and lifestyle modifications

Sidebar: Determining Statin Intensity

Mrs. Smith is a 70 year old white woman with hypertension, who presents in your Pharmacotherapy Clinic. She takes the following medications: Aspirin 81 mg PO daily, Lisinopril 20 mg PO daily and hydrochlorothiazide 25 mg PO daily. She denies use of tobacco products. You also have the following information available from her clinic visit. Her systolic blood pressure in clinic today is 120 mmHg. Her last cholesterol panel was check approximately 3 months ago and indicates a total cholesterol of 180 mg/dl and an HDL of 43 mg/dl. She tells you she has never taken medication for high cholesterol.

QUESTION 1

What is her risk status? (http://my.americanheart.org/professional/StatementsGuidelines/Prevention-Guidelines_UCM_457698_SubHomePage.jsp)

a. 3.5

b. 5.4

c. 7.6

d. 11.3

If you were able to navigate successfully to the web page and download the risk calculator spreadsheet, you found that her risk status was 11.3. Clearly Mrs. Smith requires treatment.

QUESTION 2

Which of the following would be the best choice of medication therapy to initiate?

a. Atorvastatin 40 mg because she has an indication for moderate to high-intensity statin therapy

b. Pravastatin 20 mg because she doesn't have any risk factors

c. Fluvastatin 20 mg because she's at low risk

d. Pitavastatin 1 mg because it's the cheapest

Having read the case carefully you would know that "a" is the correct response because she has an LDL between 70 mg/dl and 189 mg/dl with no diabetes and a 10-year ASCVD risk ≥ 7.5% and should be treated with moderate to high-intensity statin therapy.

QUESTION 3

She agrees to start therapy, however 8 weeks later she presents back in your clinic/store and states "I want my money back. I hurt all OVER and this medicine is the only new thing I've done. This is awful stuff." What is your correct course of action and why?

a. Give her back her money because she's clearly discontented with her therapy

b. Hold the medication and restart at a lower dose when symptoms have resolved

c. Stop the drug and tell her to limit fried foods

d. Tell her to try acetaminophen for the muscle aches because she must continue therapy

The correct answer is "b." The patient is complaining of mild to moderate symptoms that have developed during statin therapy. Based on the muscle weakness algorithm it would be appropriate to discontinue the medication at this time, monitor for resolution of symptoms, and restart the medication at a lower dose.

Summary

In conclusion, the new 2013 ACC/AHA hyperlipidemia guidelines have made several key changes in the recommendations for treating hyperlipidemia. It is now recommended that a cardiovascular risk calculator be used as an initial assessment to determine whether the patient is a candidate for statin therapy. Four groups were found by the supporting literature to benefit the most from statin therapy. Once a patient is a candidate for statin therapy, it is no longer recommended to titrate therapy to a specific LDL goal. On the contrary he/she should be on the maximum tolerable statin intensity to ensure maximum cardiovascular risk reduction. It is no longer recommended to utilize other non-statin therapy as a monotherapy or concurrently with statins due to lack of supporting evidence. Even though the new guidelines are based on the currently available supporting evidence, more studies are needed to further evaluate the effectiveness of these new guidelines.

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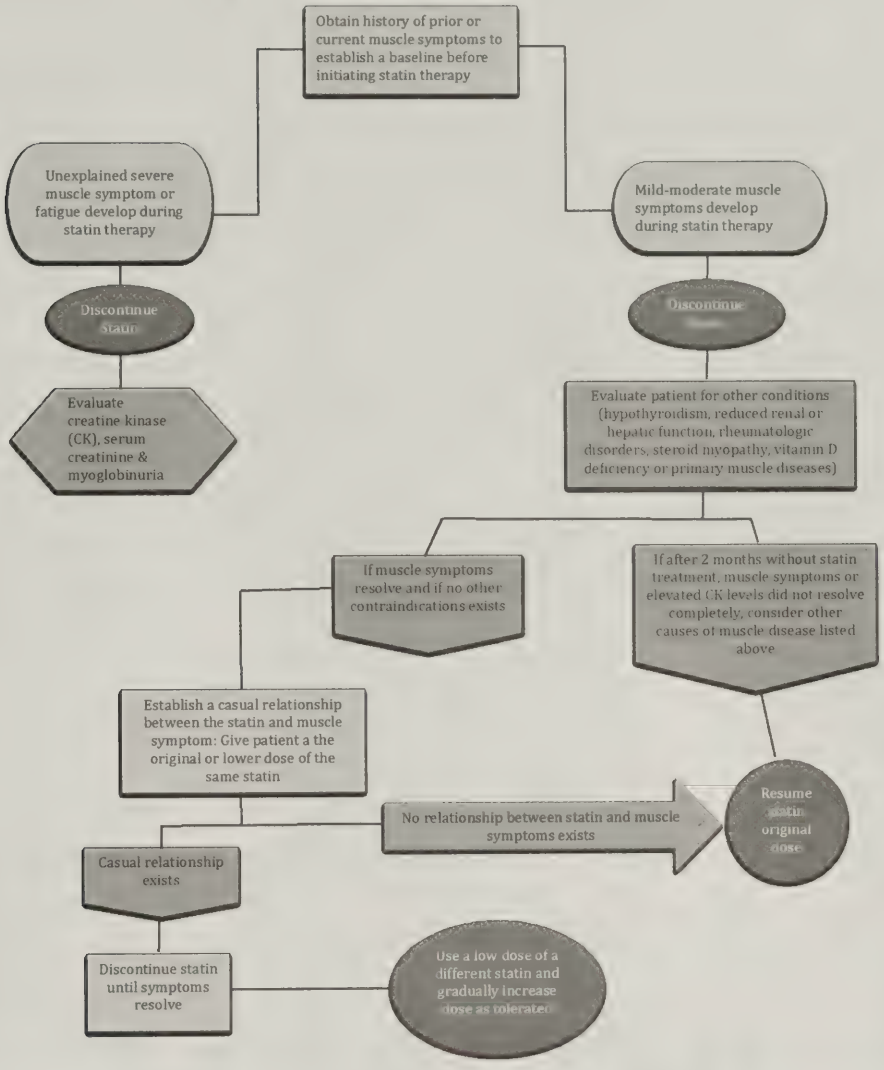
Figure 1: Muscle weakness algorithm



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Directions for taking this issue's quiz:

This issue's quiz on *New guidelines for cholesterol management: What has changed?* can be found online at www.PharmCon.com.

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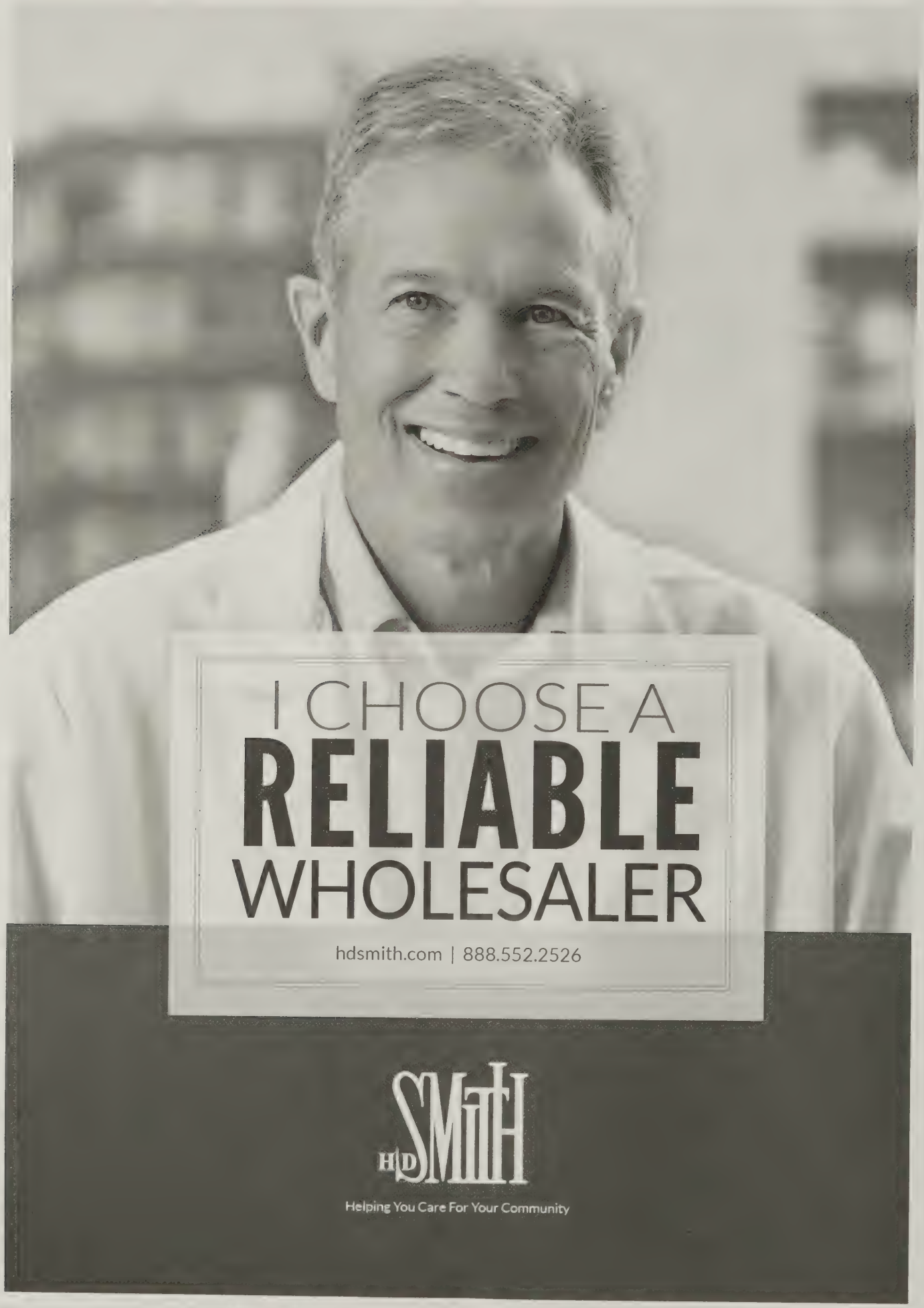
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Thank you to those members who reach out to the office to ask questions, look for resources, provide information or volunteer their time in various ways. We would not be here without you and we appreciate your support and attention.

Autumn is here and everything is starting to move again. It has been an exciting summer at MPhA and we continue to be amazed by the wonderful members that we have who are dedicated to the mission of the Association.

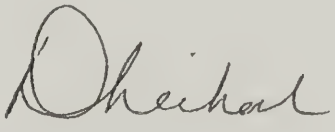
This is also the time to renew your dues for MPhA! I would like to encourage you to cross this off of your "To Do" list sooner rather than later. Dues are due by 12/31/2014 for the 2015 year. If you have any problems or questions while renewing then I encourage you to call the office at 410.727.0746 or email Shawn Collins at shawn.collins@mdpha.com. Shawn is our Membership Benefits Coordinator and she is here to help you with your renewals and any other questions you have about your MPhA membership!

We recognize that engaged members renew so we also added a committee sign-up sheet with your membership renewal form. Please be sure to take a look at all of the various committee opportunities that MPhA has to offer you! A description of all the Committees is also listed on our website. Committees are a great way to get involved in the daily workings of MPhA and to see exactly what it is that the Association does and what it has to offer you. The more you get involved, the more you will feel that MPhA is a part of your professional life. Remember that the Board of Trustee meetings are open to all members each month. There is a closed session at the end of every monthly board meeting to handle any confidential business. We encourage you to attend one of the remaining board meetings this year. The dates are October 29, November 20, and December 18. Please just let us know you are attending by RSVPing online.

What happened to the extra contributions that you used to make on the dues renewal form? These donations have decreased significantly over the years and we recognize that many of our newer members are not familiar with their purposes. Therefore, the office will be developing more information about the programs that we raise money for and soliciting for these separately. Please be on the lookout for future mailings about our supplemental opportunities to support MPhA programs, such as scholarships, survival funds, and of course our MPhA Foundation.

Mid-Year 2015 will be here soon and we have a great line up of speakers and programs. Make plans to attend on February 15, 2015 and be on the lookout for more information. The Monday Message is the best way to be sure to know what is happening with the Association. All members should receive an email from MPhA every Monday! If you are not receiving this important publication, please email Kelly Fisher at kelly.fisher@mdpha.com and ask to be added to the list. Be sure to "Like" us on Facebook, "Follow" us on Twitter, and "Connect" with us on LinkedIn. Social media and electronic newsletters are the most efficient ways for us to get quick information to our members. We are also just a phone call away! Thank you to those members who reach out to the office to ask questions, look for resources, provide information or volunteer their time in various ways. We would not be here without you and we appreciate your support and attention.

Sincerely,



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Maryland Pharmacist

Welcome!
New Board of Trustees

Dear Members,

I would like to take this time to summarize our 2013–14 accomplishments that I presented at the House of Delegates during our 132nd Annual Convention. As usual, the Convention was a wonderful time with great programs and speakers. A big thank you goes out to the MPhA Staff and the Convention Committee for all their hard work.

Membership has continued to remain stable with a slight growth in new practitioners. Deanna Tran and Ashley Moody, co-chairs of the New Practitioner Network, along with the rest of the NPN, has worked tirelessly to create fun activities and events for those that have graduated in the last five years to be involved in the Association. We are seeing the fruits of their labor in our membership numbers and know this will continue to grow. We always welcome new practitioners and pharmacists and encourage you to make the effort to encourage others you know or work with to join the Association!

The Association continues to be fiscally strong. The Kelly Fund that was established prior to our move to Montgomery Park continues to provide the bulk of our budget income. We are grateful for our relationship and investment advice from Edelman & Associates. Our Budget and Finance Committee, as well as Treasurer, Matthew Shimoda, should be commended for their job well done.

I have enjoyed working with our current Board of Trustees and look forward to continuing our work with the new 2014–15 Board of Trustees. Brian Hose will remain your Chairman of the Board and I will continue as President until the new officers are installed in February 2015. Dixie Leikach, who would have been installed as President at Convention, will continue in her role as Interim Executive Director until a replacement is found.

Our committee structure is continually evolving and we encourage you to join a committee that you find interesting. We are hoping to continue to develop our committees to be the workforce of the Association's activities and to also provide training for our future leadership. If you have any questions about our committees, I encourage you to contact me.

Many exciting events are coming up! Our Mid-Year Meeting will be held in February 2015, with a finalized date coming soon! We will present our first Technician of the Year award during this meeting so look for the nomination form in the fall.

Currently, the Association's biggest projects are the Executive Director search and the purchase of our new building space. There will be big announcements over the up-coming months so please read our *Monday Message* and *Maryland Pharmacist* for all of the latest news and information!

Sincerely,

Christine Lee-Wilson

Christine Lee-Wilson, PharmD

President

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We welcome your feedback and ideas for future articles for Maryland Pharmacist. *Send your suggestions to Kelly Fisher Maryland Pharmacists Association, 1800 Washington Blvd., Ste. 333, Baltimore, MD 21230, or email kelly.fisher@mdpha.com, or call 410.727.0746*

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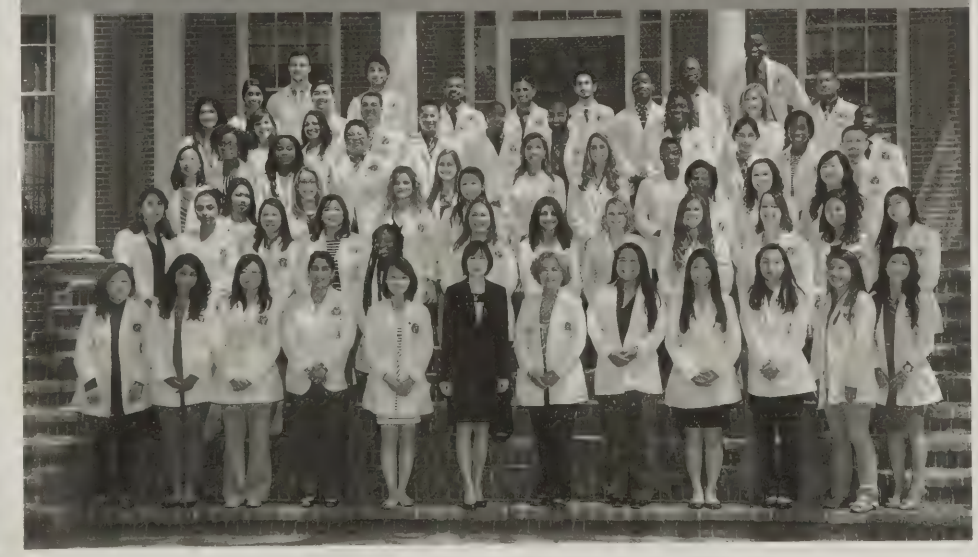

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RECOGNIZING Excellence

John Motsko & Geoff Twigg

Marsha Muhic, PharmD Candidate 2015
University of Maryland Eastern Shore School of Pharmacy
and
Cynthia J. Boyle, PharmD, FAPhA, FNAP
Professor and Chair, Department of Pharmacy Practice and Administration
School of Pharmacy, University of Maryland Eastern Shore

John Motsko

Geoff Twigg

The Maryland Pharmacists Association (MPhA) presents deserving pharmacists an array of distinguished honors and awards every June during the awards luncheon at the Annual Convention. This event allows the Association to spotlight Maryland pharmacists who are striving for excellence in pharmacy practice and promoting the advancement of the profession. One of the headline awards, the 2013 MPhA Excellence in Innovation Award, was shared by John Motsko and Geoff Twigg. They were interviewed for this article to explain how they innovated at their practice and to offer advice and encouragement to others.

Award Background

Established in 1993, this award (formerly known as the Innovative Pharmacy Practice Award) aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing MPhA pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care is eligible for nomination. The Excellence in Innovation Award is decided by the MPhA Past Presidents' Council and supported with a stipend from the MPhA Foundation.

Recipients Backgrounds

John Motsko, RPh, CDE, graduated from the University of Maryland School of Pharmacy. He worked as an Executive Sales Representative in the Diabetes Division at Eli Lilly for over thirty-five years. Five years ago he became a Certified Diabetes Educator (CDE) and earned the title of Program Coordinator and Instructor at the Apple Drugs Diabetes Center. When not busy in the pharmacy, John Motsko spends time with his wife of 44 years, children, and grandchildren.

Geoff Twigg, PharmD, BCACP, CDE, earned his Doctor of Pharmacy degree from Shenandoah University. Before becoming a pharmacist, he was hired at Apple Discount Drugs to take out the trash and refill the soda machines. For the past eight years he has been a clinical pharmacist at that same pharmacy, working in the distinctive Diabetes Center and Medication Therapy Management (MTM) Services. Although his wife often tells him that he "lives and breathes pharmacy," she always supports him and keeps him "grounded and focused."

Q&A with John Motsko and Geoff Twigg

What were your thoughts when you heard you would be recognized with the MPhA Excellence in Innovation Award?

Motsko: My initial thoughts were, wow, why us? However, when I stepped back and examined the impact we have had on patients, I thought this is great. Perhaps others will follow in our footsteps.

Twigg: My comment to Howard [Schiff] when he called to tell John and me about this honor was that it was very rewarding to be recognized by our colleagues.

What were the most important steps toward your innovative practice?

Twigg: The pharmacy owner, Jeff Sherr, was perhaps the biggest driving force. He has also been recognized in for pharmacy innovation. Jeff identifies problems he calls 'work arounds' and turns them into opportunities. I know it was a major cost as we were starting out. He allowed us time to learn, develop, and implement our programs.

Motsko: I guess you can break it down to passion, confidence, and most importantly, always putting the patient first.

What was the major barrier for your innovative practice?

Twigg: Mainly educating both our patients and local prescribers about the impact that a pharmacist can have on the overall health of a patient. Initially, many physicians viewed the pharmacist as a competitor rather than another health care provider who could help to augment their services. Often we heard from patients and prescribers alike that we were 'just a pharmacy.' We worked very hard to develop marketing materials and spend time with physicians. Once the local physicians learned how valuable a pharmacist could be, it seemed they were the ones promoting our program for us. Another big hurdle was the reimbursement issue because a lot of insurance plans did not recognize MTM as a covered service.

Motsko: We gave 'lots of free advice.'

How has working on the Eastern Shore of Maryland brought opportunities, challenges, or a unique component for your innovative practice?

Motsko: We did not have access to the number of providers or services that major metropolitan areas have. Geographically there are significant challenges for patients seeking health care. However, if these issues are identified and addressed, they can be overcome. Being somewhat isolated has enabled us to be creative out of necessity.

Twigg: Often we are able to help patients bridge the gaps in their health care. Many patients remark that the first time they had the experience of being able to sit down uninterrupted and discuss their medications and overall health with a health care professional was in the pharmacy.

What will it to take for your innovation to become a standard of practice?

Twigg: Reimbursement and provider status. Pharmacists have so much they can offer the patient. However, until they are recognized and paid accordingly I fear many of the clinical services in community pharmacy will remain simply value-added services rather than the standard of care.

How were you able to use the award stipend from the MPhA Foundation?

Motsko: I put it toward registration for American Association of Diabetes Educators (AADE) and APhA national conventions.

Twigg: I attended the Philadelphia AADE 2013 Annual Conference.

How do your colleagues describe you?

Motsko: I think my colleagues would describe me as an easy going guy, yet someone who is very passionate about what he does.

Twigg: I hope my colleagues see me as someone who truly enjoys his profession and is passionate about community pharmacy.

What advice do you have for student pharmacists at your alma mater or in Maryland?

Twigg: Always work at the top of your license. Continue to push pharmacy forward. When I graduated from Shenandoah, MTM was a buzzword. I never would have dreamed when I graduated that I would have the opportunity to do what I am doing now. I have been able to surround myself with very progressive, forward-thinking colleagues who are always pushing to expand community pharmacy.

Motsko: Find an innovative practice to work with; don't get caught up in the middle. Always try to be one step ahead of the person behind you and never slow down. Look for extra responsibilities to take on; don't punch the clock and leave on the dot. Many patients are out there who need your expertise.

You are very involved with pharmacy education and student pharmacists. What strengths and weaknesses do you see in today's student pharmacists?

Twigg: Students constantly impress me with what they are able to retain from classes. Some of the strongest students that I have had on rotations were those who may not have had the highest grades in their classes, but were able to spend time with patients and earn their trust through pharmacy interactions.

Motsko: The skill of being able to communicate is paramount for success when working with people.

What does your pharmacy future look like?

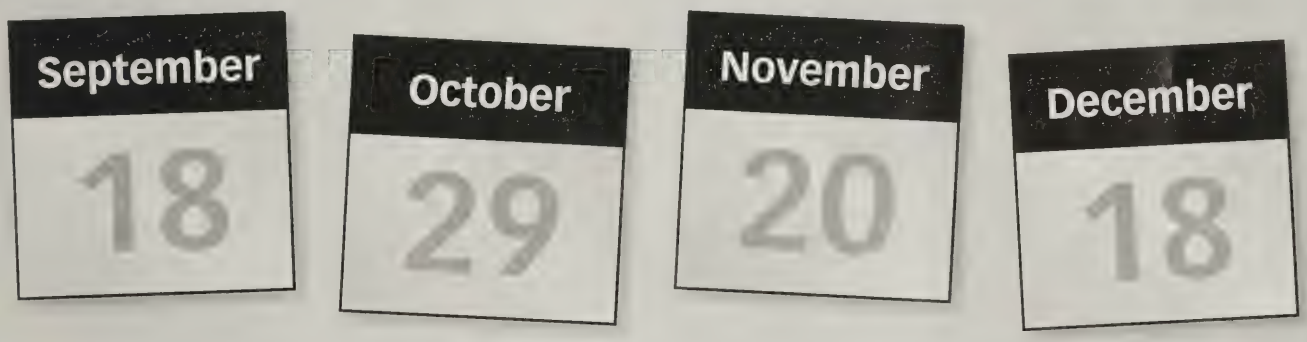
Motsko: Pharmacy HAS TO achieve provider status. We have so many skills that could benefit patients. However, we have to be compensated for our professional services. We can improve the entire health care experience. Future pharmacists need to be prepared and willing to accept this newfound responsibility. We can make a significant impact in reducing health care costs, while improving the quality of care.

Twigg: Pharmacists must be recognized as providers to help move the profession forward. I hope that when we are recognized, we will see new opportunities for community pharmacy.

MPhA
MARYLAND PHARMACISTS ASSOCIATION

Save the Date!

Board of Trustees Meetings



We hope to see you there!

Welcome to our *newest* members!

Ganiyat Awokoya
Heather Beaudy
Lena Choe
Joey Mattingly
Lana Saad

MPhA

Stay Connected!
MarylandPharmacist.org

Script Your Future Baltimore Hosts Medication Adherence Event for Health Care Professionals

By: *Script Your Future* Baltimore Field Organizers

Health care professionals face communication barriers when having conversations about the importance of medication adherence with their patients. *Script Your Future* Baltimore hosted its third Medication Adherence Experience (MAE) event on June 5 to address some of the communication issues faced by patients and pharmacists.

Script Your Future is a national campaign focused on increasing awareness about the importance of taking medications as prescribed among health care professionals and consumers. Introduced in 2013, *Script Your Future* Baltimore's MAEs are educational events that bring together health care professionals from across the region to learn about different resources and tools to help communicate the vital role medication plays in managing chronic conditions such as diabetes, asthma, hypertension, and high cholesterol amongst their patients.

On June 5, more than 50 health care professionals, including doctors, pharmacists, nurses, family caregivers, and pharmacy students attended the third MAE at the University of Maryland School of Pharmacy in Baltimore. The event focused on the quality of communication between health care professionals and patients in the retail pharmacy setting. National research findings suggest that conversations that take place in this setting are critical to improving adherence and will lead to fewer and less serious health consequences.

The event began with a networking breakfast and welcome remarks from Kathrin Kucharski, PharmD, Regional Outcomes Liaison at Sanofi. The MAE program then opened with a patient panel discussion moderated by Cherokee Layson-Wolf, PharmD, Associate Dean of Student Affairs at the University of Maryland School of Pharmacy. Three patients with chronic conditions, such as diabetes and respiratory disease, discussed their interactions with health care professionals and their medication-taking behaviors. Additionally, Dr. Nicole Brandt, PharmD, University of Maryland School of Pharmacy, joined her patient to discuss the woman's experience with juggling a complex medication regimen.

Following the panel discussion, CARE Pharmacies' Karen Kuczynski, Director of Marketing and Business Development; along with Kunjal Patel, PharmD, pharmacist at Arundel Mills CARE Pharmacy; and Sam Stolpe, PharmD, Pharmacy Quality Alliance (PQA) took the podium to discuss new strategies for measuring and improving adherence in retail pharmacies. Walgreen's Sade Osotimehin, PharmD, concluded the event by presenting examples and practices for making the most of pharmacists' often-brief interactions with patients at the pharmacy counter by applying Medication Therapy Management principles to conversations.

The third MAE was made possible by members of the *Script Your Future* Baltimore coalition and event sponsors, including the title sponsors — the Maryland Public Health Association and Novo Nordisk, along with in-kind sponsors — the University of Maryland School of Pharmacy and the Delmarva Foundation.

To learn more about Script Your Future *Baltimore, please visit: http://www.scriptyourfuture.org/pilot-cities/, or contact Kerry Owens at kowens@mghus.com.*

Photo credits this page: University of Maryland School of Pharmacy and Script Your Future *Baltimore*

Sam Stolpe, PharmD, Pharmacy Quality Alliance (PQA)

Script Your Future *Baltimore Coalition (left to right): Katie Grieco,* Script Your Future *Baltimore field organizer; Rebecca Burkholder, National Consumers League; Cherokee Layson-Wolf, University of Maryland School of Pharmacy; Kathrin Kucharski, Sanofi; Jennifer Thomas, Delmarva Foundation; Karen Kuczynski, CARE Pharmacies; and Kelly Cahill,* Script Your Future *Baltimore field organizer.*

Patient Panel (left to right): Reggie Bishop, patient; Dr. Nicole Brandt, PharmD, University of Maryland School of Pharmacy; June Kimmelshue, patient; and Robert Gaskins, patient.

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Member Mentions

Natalie D. Eddington, PhD, FAAPS, FCP, dean and professor at the University of Maryland School of Pharmacy was appointed executive director of University Regional Partnerships. Dr. Eddington will assist the University's senior vice presidents and deans regarding issues on expansion of the University's academic and research programs in Montgomery and Prince George's counties.

Brian Hose, PharmD, pharmacist and owner of Sharpsburg Pharmacy, was inducted into the Dean's Hall of Fame for Distinguished Community Pharmacists as part of the annual banquet hosted by the University of Maryland School of Pharmacy's National Community Pharmacists Association student chapter on April 24. This award recognizes a pharmacist's leadership, entrepreneurship, and passion for independent pharmacy. Brian is the youngest community pharmacist to receive the award.

Congratulations! **Chai Wang** and **Deanna Tran** were married on May 3, 2014 at the Chesapeake Bay Beach Club in Stevensville, MD. Chai is chair of the Legislative and Communications Committees and Deanna is co-chair of the New Practitioner Network. The couple graduated from the University of Maryland School of Pharmacy in 2011.

Clockwise from top: Natalie D. Eddington, Brian Hose, Chai Wang and Deanna Tran

Do you have good news to share?

Send your Member Mention to kelly.fisher@mdpha.com.

Please enclose a photo if possible.

132ND Annual Convention

Navigating the Changing Tides of Pharmacy

Clarion Resort Fontainebleau Hotel
Ocean City, MD

Some highlights of the Convention

To see all the pictures from the 132nd Annual Convention, visit the MPhA Facebook page!

Always a great time — Annual Crab Feast and Seacrets!

Monday, June 16, 2014

Congratulations to the 2014 Recipients!

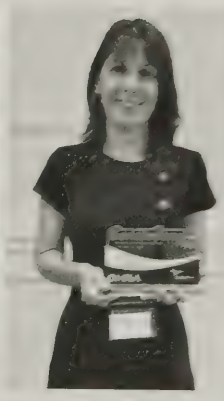
Jane Kim and **Brandon Nuziale** (not pictured) are the recipients of the MPhA Scholarship Awards presented by MPhA President Christine Lee-Wilson. **Stephanie Southard** (not pictured) is the recipient of the MPhA Foundation Scholarship Award.

Chai Wang is recognized for his service to the Association as Outgoing Speaker of the House.

Deanna Tran graciously accepted the Distinguished Young Pharmacist Award from Pharmacists Mutual Companies representative Dave DeFelice.

Chairman **Brian Hose** is recognized with the MPhA Mentor Award.

Hoai-An Truong is honored with the Excellence in Innovation Award presented by MPhA Foundation President Paul Holly. The award is sponsored by Upsher-Smith Laboratories, Inc.



Bethany DiPaula is honored with the Cardinal Health Generation Rx Champions Award. The award is sponsored by Cardinal Health Foundation.

Lynette Bradley Baker is recognized as MPhA's 2014 Honorary President by Interim Executive Director Dixie Leikach.

Mary Lynn McPherson is recognized with the Seidman Distinguished Achievement Award with her husband.

Bowl of Hygeia 2014 Award Winner

Donald Taylor is presented with the Bowl of Hygeia Award, considered the most prestigious award in the pharmacy profession, by Arnold Honkofsky. The award is sponsored by APhA Foundation and NASPA. Boehringer Ingelheim is the premier supporter.

Award Background

Established in 1958, the Bowl of Hygeia Award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. In addition to service through their local, state, and national pharmacy associations, award recipients devote their time, talent, and resources to a wide variety of causes and community service. Any MPhA member pharmacist who has not already received the Bowl of Hygeia Award is eligible for nomination.

The Bowl of Hygeia is the most widely recognized international symbol for the pharmacy profession. The Bowl of Hygeia has been associated with the pharmacy profession since as early as 1796, when the symbol was used on a coin minted for the Parisian Society of Pharmacy. The bowl represents a medicinal potion and the snake represents healing.

We are grateful for our generous

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Meet Your 2014/2015 Board of Trustees

The 2014/2015 Board of Trustees was installed during the 132nd Annual Convention on Sunday, June 15, 2014. Thank you all for your time and dedication to the Association. MPhA looks forward to your leadership and watching you all carry out our mission throughout the next year.

"Promote excellence in pharmacy practice, strengthen the profession of pharmacy, and advocate for all Maryland pharmacists."

*From left to right: Kristen Fink, Trustee; Mark Lapouraille, Trustee; Matt Shimoda, Treasurer; Nicole Culhane, Trustee; *Chris Charles, Vice Speaker of the House; *Cherokee Layson-Wolf, Trustee; Larry Hogue, Speaker of the House; *Ashley Moody, Trustee; Hoai-An Truong, President-Elect, *Nghia Nguyen, ASP Student Representative; Christine Lee-Wilson, President; Brian Hose, Chairman; Matt Shimoda, Treasurer; *Cherokee Layson-Wolf, Trustee; Nicole Culhane, Trustee; *Ashley Moody, Trustee. Not pictured: Wayne VanWie, Trustee*

**Newly installed*

CALLING ALL AUTHORS!

Write for *Maryland Pharmacist*

We are looking for authors for the following journal sections:

- Technician Corner
- Research Reports
- Review Articles
- Case Reports
- Experience
- Member Spotlight
- Commentary
- Pharmacy History
- Professional Event Promotion
- Other (Contact us with your ideas!)

Interested? Contact Kelly Fisher: kelly.fisher@mdpha.com

Journal Submission Guidelines can be found at marylandpharmacist.org under "Communications" heading

WE NEED YOUR SUBMISSIONS!

Samuel Houmes, PharmD
PGY 1 Community Pharmacy Resident

Cherokee Layson-Wolf, PharmD, CGP, BCACP, FAPhA
Associate Dean for Student Affairs and Associate Professor
University of Maryland School of Pharmacy

Swimming in circles?

A Review of the Evidence Regarding Fish Oil Supplementation

Healthcare practitioners' field questions daily from patients about whether a specific supplement is right for them or not. A question commonly asked by patients is whether fish oil would be beneficial to prevent heart disease. A few years ago the answer would have been easy, with a resounding "Yes." However, practitioners listening to recent news may begin to reconsider as select trials have found conflicting results. When comparing previous to current trials on the benefits of fish oil, it is easy to become confused. This article will aid in providing clear evidence about fish oil supplementation.

Learning Objectives: After reading this article, the learner will be able to:

1. Identify labeled and unlabeled indications for fish oil supplementation.
2. Summarize two key differences between studies involving fish oil supplementation in cardiovascular, cerebrovascular, and dysglycemia disease states.
3. Given a patient case, be able to correctly determine if fish oil supplementation is appropriate.

Key words: Supplementation, Fish oil, Cardiovascular disease

What IS Fish Oil?

What exactly constitutes fish oil? In healthcare, when professionals recommend the use of fish oil, the intent is adding a long polyunsaturated fatty acid (PUFA, also known as omega-3's) to the patient's regimen. When used as a supplement the term "fish oil" refers to specific types of PUFAs such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).[1] By using these particular fatty acids the patient will have more than the recommended daily allowance (RDA) of EPA and DHA normally obtained from the diet. The recommended daily allowance (RDA) for EPA and DHA depends on the guidelines consulted. The American Heart Association (AHA) recommends patients without documented heart disease consume at least two servings

Continued on page 20

(3-3.5 ounces) of fresh fish per week.[2] One gram of combined EPA and DHA either from supplementation or diet is recommended by the AHA in patients with heart disease. In patients with hypertriglyceridemia, defined as serum triglycerides greater than 500 mg/d3, the recommended dose is three to four grams daily.[2] It is important to consult the over-the-counter fish oil supplement labeling to verify the amount of EPA and DHA milligram content per capsule.

Many different types of fish oil products are available, as both over-the-counter and prescription supplements. Lovaza® and Vascepa® are available by prescription and are both FDA-approved to treat patients with hypertriglyceridemia.[3,4] Because these agents require a prescription, they have much stricter regulations concerning their manufacturing process. For example, the dose listed for the product correlates to the dose observed if the capsule was submitted for laboratory testing. In contrast, over the counter supplements are not subject to the same strict standards required for prescription products. This becomes evident after reviewing the Consumer Lab (CL) report for fish oil products.[5] The CL is an independent agency that tests over-the-counter products for their claimed dosage, purity, spoilage, and other parameters specific to the over the counter product.[5] Some fish oil products tested by the CL have excellent results, showing that the dosage for these products was appropriate and the product was pure and free from spoilage. Other products tested by the CL were not as pure. These products could have displayed dosages of less than 80% to greater than 260% of the claimed milligram content of EPA and DHA.[5] The products could also have contained unacceptable levels of harmful contaminants, likely a problem of poor manufacturing standards or suboptimal raw materials.[5]

Pharmacologic Effects

The mechanism of action for fish oils has yet to be clearly elucidated. Studies have shown that fish oil has a wide range of actions physiologically. Fish oil has been observed to have the following effects:

- Lipids—decreases triglycerides and increases high-density and low-density lipoproteins[6]
- Arterial compliance
- Endothelial and platelet function[7]
- Blood pressure—decreases systolic and diastolic pressures by 3-5 and 2-3 mmHg respectively[8]
- Coagulation—causes minor increases in bleeding time have been observed[7]
- Diabetes—possible effect on fasting blood glucose[9]
- Cardiac function—decreases heart rate by roughly 2.5 bpm[10]
- Electrophysiology[10]
- Effect on inflammatory factors—both EPA and DHA play a role as precursors to eicosanoids and other inflammatory mediators[11]

Table 1: Methods and Outcomes

Study & Author(s)	Study Purpose	Outcome
GISSI-P[17] Valagussa	Fish oil vs. Vitamin E vs. combination vs. placebo for primary prevention	Treatment groups that included fish oils as part of their intervention had a 10% risk reduction in cardiovascular fish oils as part of their events
GISSI-HF[18] GISSI Investigators	Fish oil with or without statin vs. placebo with or without statin for prevention of morbidity and mortality in heart failure	Small benefit for fish oil treatment
JELIS[19]	Fish oil plus statin vs. statin alone for major coronary event prevention	Fish oil group had a 19% risk reduction in major coronary events
n-3 and Dysglycemia[20]	Fish oil vs. placebo for secondary prevention in diabetics	No difference in primary or secondary outcomes
n-3 and Cardiovascular Risk Factors[21] Collaborative Group	Fish oil vs. placebo for primary prevention	No difference in primary or secondary outcomes
n-3 and Post-MI[22] Alpha Omega	Fish oil vs. placebo for secondary prevention	No significant benefit observed

Therapeutic Effectiveness

Unfortunately, fish oil supplementation does not have a clearly defined place in therapy. For example, the Adult Treatment Panel (ATP) 4 cholesterol guidelines do not recommend supplementation with fish oil in the context of cardiovascular disease prevention.[12] The European Heart Journal and American Diabetes Association recommend fish oil may be used as an agent to help with triglyceride lowering,[13,14] although only the European Heart Journal lists a suggested dose for this indication.[13] Both of those guidelines word their recommendation very lightly, stating they prefer dietary intervention and to use supplementation only if necessary. The American Association of Clinical Endocrinologist guidelines mention fish oil has a possible role in reduction of atherosclerotic plaque growth, as well as triglyceride-lowering (with a dose listed in addition), but only as

an adjunct agent.[15] Again, in these guidelines, dietary sources are preferred over supplementation.

The beginning of disease-prevention fish oil supplementation can be traced to a population study conducted in the 1980's evaluating the nutritional status of Eskimos. The researchers noticed a low baseline level of cardiovascular disease within the study population.[16] Upon comparison to other populations, they found a proportionally higher level of fish consumed within the Eskimo's diet, and the amount of fish oil consumed was calculated to be approximately 250-500 mg of EPA and DHA.[16] After analysis of this trial, researchers began to question whether supplementation with fish oil could reduce cardiovascular risk. Multiple trials were conducted, including the Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto miocardico-Prevenzione (GISSI-P), GISSI-HF, and the Japan Eicosapentaenoic Acid Lipid Intervention Study (JELIS). Refer to Table 1 for a comparison of the methods and outcomes of these trials.[17-22] These trials helped to form the original basis of evidence for fish oil supplementation.

The GISSI-P trial was conducted to determine if drug-equivalent PUFA and vitamin E were as protective as fish consumption by comparing dietary habits to a supplement-based intervention for prevention of myocardial infarction. The study enrolled patients who had a recent MI without age limits and randomized them into open-label treatment groups. One group received placebo treatments, one group received 300 mg Vitamin E, one group received 850-882 mg EPA and DHA, and the final group received both of the intervention treatments (the combination of 300 mg Vitamin E and 850-882 mg EPA and DHA). At the conclusion of the trial, the researchers noticed that the treatment groups which included fish oils as part or all of the intervention had a relative 10% risk reduction in cardiovascular events, such as death, nonfatal myocardial infarction, or stroke over the treatment groups without fish oil. This 10% risk reduction was also observed for secondary fatal events, cardiovascular disease, and coronary heart disease.[17]

The GISSI-HF trial assessed reductions in hospital admissions for patients with congestive heart failure taking 1 gram of fish oil daily. The study enrolled patients with New York Heart Association Class II-IV regardless of cause, and assigned patients to either 1 gram of fish oil daily or placebo. After the trial was completed, the researchers observed a hazard ratio of 0.91 (p=0.041) for the fish oil treatment and 0.92 (p=0.009) for the placebo treatment, suggesting a small benefit for fish oil. The authors calculated a number needed to treat (NNT) of 56 patients treated with fish oil for 3.9 years to avoid one death, or 44 patients to avoid one event such as death or admission due to cardiovascular cause.[18]

The JELIS trial evaluated the primary prevention of coronary artery disease with long-term use of fish oil in hypercholesteremic patients. Participants were randomly assigned to receive 1800 mg of EPA daily fish oil or placebo. Both groups were concurrently taking statin therapy. The primary endpoints were any major coronary event and non-fatal events such as unstable angina, angioplasty, stenting, or coronary artery bypass graft (CABG). Upon data examination, the authors noted patients in the fish oil intervention group with a history of coronary artery disease had an approximate 19% risk reduction in major coronary events, defined as non-fatal myocardial infarction, unstable angina, and events of angioplasty, stenting, or coronary artery bypass grafting.[19] These three trial observations conflict with the following trial conclusions concerning fish oil supplementation.

The purpose of the ORIGIN trial, published in 2012, was to determine if long-term fish oil supplementation would decrease cardiovascular events in diabetic populations.[20] It was a randomized control trial and included patients who were 50 years or older, had diabetes or an impaired fasting glucose or impaired glucose tolerance test, a previous myocardial infarction (MI), stroke, revascularization, angina, microalbuminuria, left ventricular hypertrophy, a 50% stenosis of a coronary artery, or an ankle-brachial index less than 0.9. Patients were excluded if they were unwilling to stop current fish oil use, had an hemoglobin A1c >9%, a coronary artery bypass graft (CABG) in the previous four years, heart failure, or a cancer diagnosis that may have affected survival during the course of the trial. Patients were randomized to an olive oil placebo or to 1 gram of combined EPA and DHA daily. The primary study endpoint was death from cardiovascular cause. Secondary endpoints included the composite of death from cardiovascular cause, nonfatal MI, nonfatal stroke, death from any cause, or death from arrhythmia. The research team observed no significant difference in both primary and secondary outcomes. Upon generation of Kaplan-Meier survival curves, the data points for both the intervention group and placebo group appear to overlap, further suggesting fish oil supplementation provided no benefit in this study population.[20]

The Risk and Prevention Study Collaborative, published in 2013, studied whether fish oil would display a risk reduction in patients with multiple cardiovascular risk factors.[21] It was a randomized, placebo controlled trial that included participants with four or more of the following, or in patients with diabetes having at least one of the following: 65 years old or older, male, preexisting hypertension or treatment, preexisting hyperlipidemia or treatment, smoking, obesity, family history of premature disease in a male relative less than 55 years old (or a female relative less than 65), atherosclerotic disease (defined as angina, peripheral artery disease, a history of stroke or a transient ischemic attack, or a prior revascularization) or the practitioner held the opinion the patient had a high cardiovascular disease risk. Exclusion criteria included a past history of MI,

Continued on page 22

a fish oil allergy, current pregnancy, an inability to give informed consent, or poor short term prognosis affecting survival during the trial. Patients were randomized to receive either one gram of fish oil or placebo olive oil. The primary study endpoint was originally planned as a cumulative rate of death, nonfatal MI, or nonfatal stroke, with secondary endpoints of composite of time to death, death from CHD, and sudden death from cardiac cause. These were changed to primary endpoints of time to death from CV cause, or hospital admission for CV cause, with secondary endpoints compromising the original secondary endpoints with the previous primary endpoints. This change occurred mid-study due to participants not meeting the expected event rate for the trial. As in the ORIGIN trial, this trial observed no significant difference in primary or secondary endpoints. Again, on Kaplan-Meier survival curves the data points for intervention and placebo groups appear to overlap, signifying no major difference between treatments. Notably, upon subgroup analysis in this trial two instances were found where fish oil supplementation provided a small but significant benefit. The research team noted the hospitalization admission rate for patients with heart failure taking fish oil was lower and also found female patients taking fish oil supplements were less likely to be admitted to a hospital for a cardiovascular cause, and had a lower risk of death overall.[21]

The Alpha Omega trial was completed to determine whether low-dose fish oil and/or alpha–linoleic acid (ALA, a precursor to EPA and DHA) had a risk reduction effect in patients who already had a myocardial infarction.[22] It was a randomized control trial which included patients aged 60-80 years old with a clinical diagnosis of MI in the past decade. Participants were excluded if they were unable to consume less than 10 grams of margarine daily (for reference, one stick of butter is approximately 110 grams), prior or current use of fish oil, an unintended weight loss, or a cancer diagnosis with less than one year of life expectancy. The placebo group received margarine containing the recommended daily values of EPA, DHA, and ALA. The fish oil intervention group received RDA plus 400 mg of fish oils. The ALA intervention group received RDV plus 2 grams of ALA. A third combined intervention group received RDV plus 400 mg of fish oils and 2 grams of ALA. The primary endpoints for the study included non-fatal or fatal cardiovascular disease, percutaneous coronary intervention, or CABG. Secondary endpoints included incident cardiovascular disease, fatal cardiovascular disease, fatal coronary heart disease, ventricular-arrhythmia related events, and death from any cause. Across all of the groups, no significant benefit was observed in the fish oil, ALA, or combined intervention groups over placebo. In the Kaplan-Meier survival curves, the data points were again overlapping through the course of the study. ALA appeared to have a slight advantage in the Kaplan-Meier survival curves for major CV events in women towards the end of the study, but this was not significant prior to trial conclusion. The research team did conduct a post-hoc exploratory analysis of patients with and patients without diabetes. Within the diabetic subgroup, there were statistically significant reductions in incident cardiovascular disease, death from coronary heart disease, as well as ventricular-arrhythmia-related events. These risk reductions were observed for both the fish oil and ALA intervention groups. The authors noted that even though the significance of the data was comparable to the data observed in the GISSI-P trial, this was only noticed after unblinding of the data.[22]

So What's the Bottom Line?

Considering all of this information, it is difficult to draw definitive conclusions based on the data. When closely examining the trials, many differences are noted. First, the trials all had different stated purposes (refer to Table 1)[17-22]. To definitively refute a scientific claim, a study would have to be conducted in the same manner and find conflicting results. Since this did not occur, the conflicting results may be viewed with caution. When considering the outcomes of a primary prevention trial, it is difficult to make a claim on secondary prevention effects, or to extrapolate results from a specific study population to all populations or for different indications.

Another point of contention is the recording and use of concurrent

Table 2: Concurrent Cardioprotective Therapies

Study & Author(s)	ACE-I/ARB	Aspirin	Beta-Blocker	Statin
Greenland Eskimos[16]	—	—	—	—
GISSI-P[17] Valagussa	Yes	Yes	Yes	No
GISSI-HF[18] GISSI Investigators	Yes	Yes	Yes	Yes
JELIS[19] Yokoyama	Yes	Yes	Yes	Yes
n-3 and Dysglycemia[20] ORIGIN Trial	Yes	Yes	Yes	Yes
n-3 and Cardiovascular Risk Factors[21] Collaborative Group	Yes	Yes	Yes	Yes
n-3 and Post-MI[22] Kromhout	Yes	Yes	Yes	Yes

Table 3: Study Differences

Study & Author(s)	Dietary Fish	Fish Oil Dose	Follow-up
Greenland Eskimos[16]	30 grams fish/daily	—	—
GISSI-P[17] Valagussa	Not studied	850-882 mg EPA:DHA:* no data Ratio: 1:2	42 months
GISSI-HF[18] GISSI Investigators	Not studied EPA:DHA: no data Ratio: 1:2	850-882 mg	36 months
JELIS[19] Yokoyama	Not studied	1800 mg EPA alone, no DHA	48-72 months
n-3 and Dysglycemia[20] Bosch	Not studied	1 gm. EPA:DHA ~84% Ratio: 1.2:1	72-96 months
n-3 and Cardiovascular Risk Factors[21] Roncaglioni	Not studied	1 gm. EPA:DHA: >85% Ratio: 0.9-1.5:1	60 months
n-3 and Post-MI[22] Kromhout	Not studied	RDV** + 400 mg EPA:DHA: ~3% Ratio: 3:2	40 months

*EPA – eicosapentaenoic acid. DHA – docosahexaenoic acid

**RDV – recommended daily value

cardioprotective therapies (refer to Table 2). Unfortunately, in comparison to the ORIGIN, Alpha Omega, and Risk Prevention trials, the early trials were not as consistent with the use of statins.[20,21,22] During the GISSI-P study, statin therapy was not considered appropriate standard of care.[17] In GISSI-HF, patients were also randomized to either placebo or 10 mg of rosuvastatin (in addition to receiving fish oils or placebo as well).[18] The JELIS trial was the only early trial assessing the comparison of benefit in statin and placebo combination treatment versus statin (10-20 mg of pravastatin or 5-10 mg of simvastatin) and fish oil.[19] Given that each of the early trials displayed a benefit in favor of fish oil and each of the recent trials, with notably increased use of statins and at higher dosages, [20,21,22] found little or no benefit of fish oils, a question arises about the impact of statin therapy on cardiovascular disease and prevention. Although the benefits of statin therapy alone have been well documented, the core issue is if the addition of fish oils provides additional benefit when combined with statin therapy.

The amount of study follow-up was notably different between trials (refer to Table 3). Follow-up periods with the trials ranged from 40 months up to 96 months. While not extraordinarily different, the amount of time each trial had to observe event rates is an important factor to consider before comparing trials on a head to head basis.

Assessment of dietary habits and fish consumption was not rigorously controlled in each of the clinical trials (see Table 3). For example, each of the trials described an attempt to control a participant's diet during the course of the study through the use of dietary counseling. However, properly assessing dietary habits is difficult in these larger studies. In order to completely and accurately assess a patient's dietary habits, it would require constant observation of the participant enrolled in a trial. This is not feasible, as it would require either institutionalization of the participant or require a team member to observe the individual all day. While less than ideal, questionnaires allow for subjective assessment of dietary habits. This, however, inevitably decreases the quality of the data recorded and could be considered a confounding factor. Another factor is the use of olive oil in the recent trials.[20,21] It has been well documented that olive oils have beneficial effects on health as demonstrated in the Mediterranean diet. The recent trials null results could be exaggerated by the use of an olive oil, which has protective heart effects.

A final inconsistency between trials was the fish oil dose utilized for each study (refer to Table 3). Both the total dose of fish oil used for supplementation, as well as the ratio of EPA to DHA varied among the trials. These inconsistencies make it difficult to compare trial results.

What's The Bottom Line?

Based on the currently available evidence, a clear recommendation is difficult to determine. An accurate recommendation for patients inquiring about the use of fish oil may be that the addition of fish oil to their current drug regimen would likely not provide a risk reduction benefit. Having said that, the patient may choose to pursue fish oil supplementation despite the lack of strong beneficial evidence particularly since fish oil has a relatively benign side effect profile. As with all dug therapy, benefits and burdens of therapy must be considered, including the financial cost of therapy. Ultimately, to assess the true benefit of fish oils on cardiovascular disease prevention vs. the current standard of care, a head to head trial comparing statin therapy alone to statin therapy with added fish oil would be needed.

Continued on page 24

Sidebar Case: "Clearly Confused"

AT is a 58 year old African American woman who approaches the pharmacy counter with a bottle of fish oil in hand. She asks to speak with the pharmacist, and inquires whether or not fish oil will help her stay healthy. Luckily, she gets all her medications at this pharmacy, and just-so-happens to have her most recent lab results from her primary care visit. She states she has a past history of hypertension, diabetes, dyslipidemia, migraines, and seasonal allergies. She reports both her mother and father had a history of heart disease.

MEDICATION PROFILE		
DRUG	DOSE	DIRECTIONS
Lisinopril	20 mg	Take 1 by mouth once daily
Metoprolol ER	50 mg	Take 1 by mouth twice daily
Janumet	50/500 mg	Take 1 by mouth twice daily
Aspirin	81 mg	Take 1 by mouth once daily
Simvastatin	40 mg	Take 1 by mouth at bedtime
Loratadine	10 mg	Take 1 by mouth once daily as needed
Excedrin Migraine	250/250/65 mg	Take 2 by mouth every 6 hours as needed. Maximum of 8 per day

LABS
Blood Pressure – 128/78 mmHg
Heart Rate – 65 bpm
Respiratory Rate – 15 bpm
Total Cholesterol – 187 mg/dL
HDL – 48 mg/dL
LDL – 105 mg/dL
Triglycerides – 168 mg/dL
Hemoglobin A1c – 6.4%

QUESTION 1

What recommendation would you give AT whether she should start taking fish oil?

a. AT should start taking fish oil at a dose of 4 grams daily.

b. AT should start taking fish oil at a dose of 1 gram daily.

c. AT does not need to take fish oil.

d. AT should bring this question up at her next visit with her primary care physician.

QUESTION 2

At what serum triglyceride level would fish oil supplementation be considered appropriate for treatment of hypertriglyceridemia?

a. > 250 mg/dL

b. > 500 mg/dL

c. > 750 mg/dL

d. > 1000 mg/dL

QUESTION 3

What counseling would you offer to AT if she chooses to begin fish oil supplementation today?

a. She can expect a lowered lifetime risk for cardiovascular disease.

b. She can expect to see a decrease of her low-density lipoprotein serum concentrations.

c. She likely will be taking a supplement without proven risk reduction in cardiovascular disease states.

d. She may notice her blood pressure and heart rate will increase while taking supplements.

The answer to question1 is "C." Based on the analysis of the Alpha Omega, Risk Prevention, and ORIGIN trials, cardiovascular risk reduction does not appear to be clinically or statistically significant with fish oil supplementation. D is incorrect, because pharmacists are clearly able to accurately answer questions about supplements. A is the approved dose for hypertriglyceridemia treatment. B is a dose recommended by the AHA for patients with heart disease.

As discussed in the article, the clinical definition of hypertriglyceridemia is a serum triglyceride level above 500 mg/dL, therefore the answer is "B."

Regarding question 3, the Alpha Omega, Risk Prevention, and ORIGIN trials did not display cardiovascular risk reduction, therefore A is incorrect. B is incorrect because LDL levels are expected to increase with fish oil supplementation. Likewise, D is incorrect because select studies showed a decrease in blood pressure and heart rate with supplementation. Therefore the correct answer is "C."

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CONTINUING EDUCATION QUIZ

PharmCon is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. A continuing education credit will be awarded within six to eight weeks.

Program Release Date: 7/8/2014

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This program is Knowledge Based – acquiring factual knowledge that is based on evidence as accepted in the literature by the health care professionals.

Directions for taking this issue's quiz:

This issue's quiz on *Swimming in Circles? A Review of the Evidence Regarding Fish Oil Supplementation* can be found online at www.PharmCon.com.

(1) Click on "Obtain Your Statement of CE Credits for the first time.

(2) Scroll down to Homestudy/OnDemand CE Credits and select the Quiz you want to take.

(3) Log in using your username (your email address) and Password MPHA123 (case sensitive). Please change your password after logging in to protect your privacy.

(4) Click the Test link to take the quiz.

Note: If this is not the first time you are signing in, just scroll down to Homestudy/OnDemand CE Credits and select the quiz you want to take.

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On the Hill for RxImpact Day

Courtney Lanehart, PharmD Candidate 2017, Notre Dame of Maryland University School of Pharmacy

In my second month of my first year in pharmacy school at Notre Dame of Maryland University School of Pharmacy (NDMU SOP), I received an email about an initiative to advocate for pharmacy at the national level with the National Association of Chain Drug Stores (NACDS). NACDS was accepting applications from students across the country to participate in their 6th annual RxImpact Day on Capitol Hill in Washington, D.C. in March 2014. I jumped at this opportunity and submitted my CV and application, just barely making the cut-off date. A few weeks later I was informed by Ifeoma Ibe, another student from NDMU SOP, that she and I were chosen to participate! I was ecstatic about being selected, but I definitely underestimated how powerful this event would be.

On March 12, 2014, the students chosen for RxImpact Day arrived at The Liaison Capitol Hill Hotel. We were welcomed into RxImpact "U" Academy, which was an informational session and workshop covering the history of RxImpact Day, leadership and advocacy skills, an insider's view of how Capitol Hill works, and discussions about legislation for which we would be advocating. We also participated in mock legislative visits with faculty mentors. This program was extremely beneficial in preparing the students for the day on the Hill. I applaud NACDS for the excellent RxImpact "U" Academy program.

Early in the morning on March 13, 2014, all of the RxImpact Day participants, over 400 from 40 states, gathered for breakfast and met with their teams. I belonged to Team Maryland comprised of myself & 8 others, including Dr. Cynthia Boyle and Eric Barbye from University of Maryland Eastern Shore, community pharmacists with some of their interns and experiential students from the University of Maryland School of Pharmacy, and a pharmacist who is a senior manager of pharmacy purchasing. Team Maryland had five meetings at various congressional offices and two drop by appointments. We exclusively met with legislative assistants throughout the day, although we had a photo opportunity with Congressman Chris Van Hollen. I was exceptionally surprised at how well informed the legislative assistants were on the topics we presented. I was expecting to go into the appointments and have to explain everything, but shockingly, we did not. I was also pleased to see that most of the assistants were receptive to our issues. Specifically Walter Gonzales, Health Legislative Assistant for Congressman Dutch Ruppersberger, was well-informed and encouraging. We hit a little resistance throughout the day, but Team Maryland worked together to answer questions and provide perspectives.

> We need committed pharmacists and student pharmacists to continue advocating for our profession…this is our job…this is our life. Take pride and get what you want out of it.

Two days prior to RxImpact Day, H.R. 4190 was introduced into the House of Representatives. This bill, if passed, would amend the Social Security Act of 1935 to list pharmacists as Medicare Part B providers. This was the hot topic of our visits! H.R. 4190 is such an important piece of legislation for the pharmacy profession and for patients. This could be a fundamental change to how pharmacists practice throughout the country. It was an honor to lobby for this legislation. We might have set-backs along the way to bill passage, but we'll stand up, brush off our white coats, and keep advocating.

I am in my first year of pharmacy school and thus far I have had the chance to advocate at the state and national levels. I **AM** an advocate for the pharmacy profession, and I plan to keep it that way. However, we need more! Cultural anthropologist Margaret Mead once said, "Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it's the only thing that ever has." We need committed pharmacists and student pharmacists to continue advocating for our profession … this is our job … this is our life. Take pride and get what you want out of it. To the student pharmacists out there like me, listen up! This is our future on the line … advocate for patients, other student pharmacists, and yourself.

NACDS RxImpact Day planners do a wonderful job planning and organizing this successful event. I would like to thank NACDS for giving me this incredible opportunity, and I appreciate all the effort invested in the program for student pharmacists. As long as we continue advocating and don't lose sight of patients' health, we can achieve provider status.

For further reading, please access the following two articles from drugstorenews.com:

http://drugstorenews.com/article/nacds-rximpact-shines-spotlight-pharmacists-increasing-role-delivery-healthcare-services

http://drugstorenews.com/article/bipartisan-house-bill-seeks-designate-pharmacists-healthcare-providers-medicare

> One thing that has not changed is that we are ONE Association for ALL pharmacists. Pick ONE way you can get involved in your Association this year.

Today's world is fast and exciting. There are a lot of changes and nothing seems to stay the same. Some think this is a great advancement in mankind and others struggle to keep up. The Maryland Pharmacists Association tries to blend the best of the new and the old.

We have just come home from our 132nd Annual Convention in Ocean City. Same location, different vibe. There were some changes and some traditional events. Topics for CE were on trend with the conversations in the pharmacy profession, as well as the tried and true programs. New faces joined us and many familiar faces were still around. We had new and exciting fundraisers for the MPhA Foundation and raised $1,400! Your new Board of Trustees were installed, however, your President and Chairman of the Board remained the same. A survey will go out to those who did and did not attend so that we can get feedback on your experience. We encourage you to return it quickly!

The office has seen some changes this year. Our Member Benefits Coordinator, Shawn Collins, and Marketing Coordinator, Kelly Fisher, are new additions to our staff. Our Office Manager, Elsie Prince, remains in her position still after 18 years of service to our Association. We are in the process of finding the right person for the job as our Executive Director. Howard Schiff served this Association well for many years. Peggy Funk showed us how marketing and communication can make our organization stronger. Kristen Fink is graciously chairing our Selection Committee and the Committee is a diverse collection of members in varying areas of pharmacy practice. The Committee is working hard and we look forward to welcoming their choice.

During Convention, the Board of Trustees voted to move forward with the purchase of a building. This will provide us with permanent space for our museum, office staff, and meeting space. Many years ago, our leadership set up a great opportunity for the Association and your current leadership is doing everything it can to keep the strong tradition of fiscal responsibility and foresight.

Lots of changes and lots of things that stay the same. One thing that has not changed is that we are ONE Association for ALL pharmacists. Pick ONE way you can get involved in your Association this year. Will it be a committee, or a new event, or asking a colleague to join as a new member?

I look forward to hearing what your ONE new activity will be this year because we are …

Stronger by Association —

Dixie Leikach, RPh, MBA, FACA
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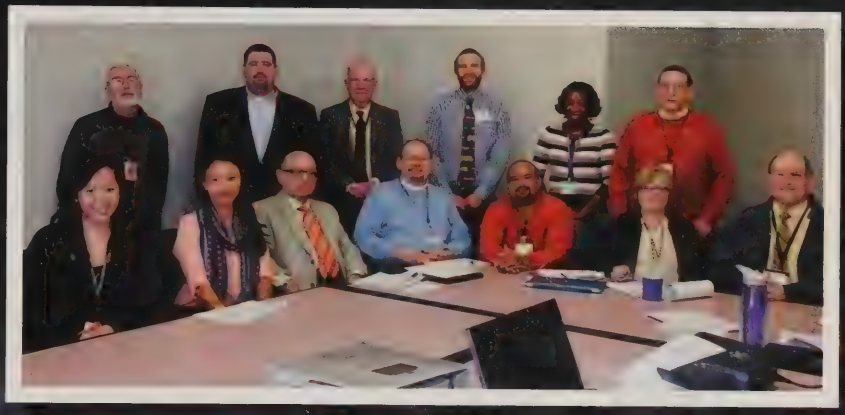

Board of Pharmacy Emergency Preparedness Taskforce

"You cannot predict where evil will raise its head, but you can be prepared for it"

— Russell Pearce

The profession needs you; take the plunge, and help us out.

Dear MPhA members,

This past winter my knowledge and involvement regarding the legislative process grew immensely. For starters, I became more involved in the Maryland Pharmacy Coalition. I volunteered to assist in writing position statements and to be on the team that developed the leave behind for Legislative Day. I was given many opportunities to provide testimony for a number of bills involving pharmacy.

Through my involvement this year I was able to learn more about the overall process, the politics, and what occurs during the Legislative Session. At times it was overwhelming, but I had a number of pharmacists and resources available to assist me.

Most importantly, I learned about how critical it is for pharmacists, technicians, and students to represent the pharmacy profession. If you have taken the trip to Annapolis in the past to testify on behalf of the pharmacy profession I would like to thank you. You are the reason I am able to provide immunizations and have a Drug Therapy Management Protocol in place.

Until this year, I took the safe approach to the advocacy role; I was silent. Advocacy to me felt like diving into murky water, uncomfortable. I know many pharmacists feel the same way. After this year, I learned the silent approach does not work in Legislation. Do not let your insecurities get in the way of being involved in speaking up for the profession. The profession needs you; take the plunge, and help us out.

When you renew your membership for 2015, consider checking the "Yes" box next to "Interesting in Testifying during the Legislative Session."

I know I still have lots to learn about the process. This year was a great experience and I am committed to staying involved in advocacy in the future.

Warm regards,

Christine Lee-Wilson

Christine Lee-Wilson, PharmD

President

Pharmacists testify in Annapolis on the PBM-Pharmacy Contracts-Payments bill, SB952.

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MARYLAND PHARMACISTS IN EMERGENCY PREPAREDNESS

A Brief History

By: G. Lawrence Hogue, PD
Donald Taylor, RPh
Arnold Honkofsky, PD

The Maryland Board of Pharmacy has been actively planning for emergency events since shortly after the 9/11/2001 attacks in New York and Washington D.C. The Maryland Board developed a Bioterrorism Committee to start planning to be able to respond to any event happening in Maryland and to help protect the health and welfare of Maryland citizens. With the help of Board's Executive Director, LaVerne Naesea, and an ever changing series of State personnel assigned to work with the Board, that Committee became the first Bioterrorism Committee among the medical disciplines in the State. The Board's Bioterrorism Committee's initial project was to advertise for pharmacist volunteers from all areas of the State. The Board sent requests by mail and made phone calls and in short order had well over 100 volunteers.

The early emphasis was on treatment for anthrax or other deadly toxins and several practice exercises were held. One in particular was a full scale clinic set-up in which pharmacists dispensed 'medicine' and gave advice to people who had 'found themselves in disaster areas.' Pharmacists were designated as 'leads' for each area and several went to Baltimore City and the various County Health Departments to explain how the Committee could help with their local planning.

Then came Hurricane Katrina in 2005. Just a few hours after the first phone call, the Board asked for volunteers to go to the Louisiana area, in particular to Jefferson Parish where the Maryland National Guard, along with well over 100 medical discipline volunteers (who had been sworn in as Guardsmen for the two week anticipated duration of the mission) took control of the county. The people who did not get out in time had no electricity other than emergency generators, no open stores, no land line telephones, essentially no way to exist except through the services provided by the volunteers. These services included medical services and supplies, food, drinkable water, and ice to help them in the 90+ degree heat and high humidity. The Board's volunteers were billeted in an abandoned hospital, which was rank from the flood waters that had gone through. It took over a week to make it fully habitable. In the meantime, six clinics were set up in the county and a pharmacist was assigned to each group when there were enough (the Board sent a total of 13 Maryland volunteer pharmacists over approximately 2 months). They helped physicians decide what medicine to dispense since the medical supplies were severely limited, cleaned up areas of the hospital including the pharmacy, sorted the medications that the National Guard brought in from the samples in abandoned physician hospitals, and ordered drugs needed from the Federal Emergency Management Agency. The last function was extremely frustrating as supplies coming in were almost totally inept.

> "You cannot predict where evil will raise its head, but you can be prepared for it"
>
> — *Russell Pearce*

That experience changed the focus of the Bioterrorism Committee dramatically. No longer was the Board only concerned with getting Cipro as protection against anthrax, but was now concerned with making

sure that citizens of affected areas could get all types of urgently needed drugs when needed – drugs like anti-hypertensives and anti-diabetics. The Bioterrorism Committee morphed into the Board's Emergency Preparedness Task Force (EPTF). Up to this point, the Board had been solely responsible for recruiting and training pharmacy volunteers. The Department of Health and Mental Hygiene's (DHMH) Office of Preparedness & Response (OP&R) started the Maryland Professional Volunteer Corp (MPVC), and began recruiting volunteers from all of the medical disciplines. The OP&R director began attending the Board's EPTF monthly meetings, contributing to the EPTF's knowledge of State plans and activities.

OP&R requested an EPTF member to assist in the first Center for Disease Control and Prevention (CDC) meetings designed to locate a suitable facility for a State Receipt, Stage, Store (RSS) site. The RSS site is a CDC approved site designed to be utilized as the location to receive federal assets following an emergency event. The EPTF was also asked to participate in writing the first State Strategic National Stockpile (SNS) plan. That plan was required to meet specified federal requirements, and became the basis for all future emergency planning in Maryland.

While the search for a suitable RSS site was progressing, a massive earthquake occurred in Haiti in 2010. An EPTF pharmacist member

Board of Pharmacy Emergency Preparedness Taskforce

Bottom row, left to right: Dorothy Sheu, Stephanie Parsons, Mel Rubin, Phil Cogan, Sajal Roy, Janet Seeds and Arnie Honkofsky*

Top row, left to right: Reid Zimmer, Kevin Jura, Larry Hogue, Zack Sherr, Charmaine Rochester and Don Taylor*

** Department of Health and Mental Hygiene Operation Staff*

volunteered to go to Haiti to help wherever the need was the greatest. That member worked in an improvised Neonatal Intensive Care Unit. Conditions were hot and work areas certainly not sterile. *"It truly was "Pharmacy at the Improv", or perhaps better described as "MacGyver Pharmacy." Examples of this include making solutions and suspensions for oral use from tablets and capsules, making oral drugs from IV drugs, deciphering medication names labeled in different languages, creating D5%/0.45% "from scratch" without the luxury of available concentrated sodium chloride!"* Help for the pharmacists and nurses often consisted of volunteer college students trained on the fly. As was the case in Katrina, volunteers reported that the experience of "making a real difference in people's lives" made any problems encountered more than worthwhile.

The massive devastation in Haiti highlighted the fact that just recruiting professional volunteers was not sufficient for large scale events, and the MPVC was changed to MD Responds, which includes volunteers from all personnel arenas – not just medical personnel. The Director of MD Responds continues to attend the Board's EPTF monthly meetings and encourages pharmacy participation at the State planning levels.

Once a Maryland RSS site was approved, an OP&R Committee was formed to begin planning for developing procedures for future receipt and storing of purchased medical assets, in addition to any assets received from the federal stockpiles. An EPTF pharmacist member was recruited to serve as a member of the newly formed State RSS Task Force. That member currently attends RSS Committee meetings, and the EPTF is actively involved in revisions to the State SNS plan. The latest rewrite of the State SNS plan has updated that plan to include an

RSS Pharmacy Volunteers – State Distribution Exercise

Photo 1
RSS Pharmacy Volunteers – State Distribution Exercise

Photo 2
Mel Rubin at Jefferson Parish helping out after Hurricane Katrina

Photo 3
UMES Student POD Exercise

all hazards approach to emergency preparedness. In coordination with the federal plan, the new State plan in now referred to as the Emergency Medical Countermeasure Dispensing and Distribution Plan (eMCM). Pharmacy has defined RSS roles written into the eMCM plan: (1) overseeing all Controlled Dangerous Substance functions; (2) dispensing prophylactic medications to RSS personnel and their families (if required); (3) overseeing any RSS repackaging operations; (4) quality assurance of all outgoing orders prior to loading onto delivery vehicles; and (5) serving as a resource for medication related questions/issues.

The EPTF has been recognized by OP&R, DHMH and CDC as being an integral part of emergency planning in Maryland. The EPTF has become a front line resource for State mediation related questions, as well as storage and distribution issues. Core members of the EPTF are required to take mandatory training courses as required by CDC. Currently, the EPTF still meets each month, participates in RSS planning, updates the State's emergency plans and, participates in State emergency preparedness drills and exercises. One member of the EPTF has been presenting emergency preparedness lectures to student pharmacists at all three pharmacy schools in Maryland. These lectures highlight pharmacy roles in Maryland emergency preparedness planning and training.

Another member introduced the innovative concept of conducting Point of Dispensing (POD)* exercises for student pharmacists. The inaugural drill, the first ever conducted at a Maryland school of pharmacy and possibly the nation, was conducted at the University of Maryland Eastern Shore School of Pharmacy (UMES) in June 2013. Another drill was held in September at UMES and was followed with an exercise at Notre Dame of Maryland University in November. These exercises serve as introductory emergency preparedness courses to pharmacy students about "Pharmacy Roles in Emergency Preparedness in Maryland." Students get to observe a sample POD setup and participate by manning 3 different POD stations as well as play patients who are picking up medications for their entire families. Stations manned by the students include registration, medication triage, and dispensing. Students that have participated in a past POD exercise are then encouraged to participate in future exercises as facilitators helping the next year's pharmacy students during their POD exercise.

The EPTF remains active in emergency preparedness planning and exercises in all areas of the State. During the September 2013 State

Distribution Exercise, the EPTF and pharmacy volunteers were recognized for their participation. In the summary for that exercise, the pharmacy volunteers were singled out as a *"key group responsible for the success of RSS operations. Several strengths were identified during their evaluation during exercise operations. Especially impressive was the supportive role played by the BOP Executive Committee, BOP Commissioners and the Board's Emergency Preparedness Task Force. This was the first time such a supportive and integrated role by a Maryland professional board has been documented and recognized. Certainly, this involvement and participation should be encouraged and continued."* The EPTF has also worked with several county health departments and Baltimore City in drills and exercises held at the local levels. The Task Force does have student pharmacist representation and encourages any interested pharmacist, student, or pharmacy technician to attend the monthly meetings.

Are YOU prepared? Do YOU have an emergency preparedness plan? Would YOU consider donating some of your time to be an EPTF member? If so, contact Janet Seeds at janet.seeds@maryland.gov.

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* PODs are designated locations in a community such as schools, fire halls, hospitals, etc. where residents would be directed to go to receive medications and supplies in a declared emergency.

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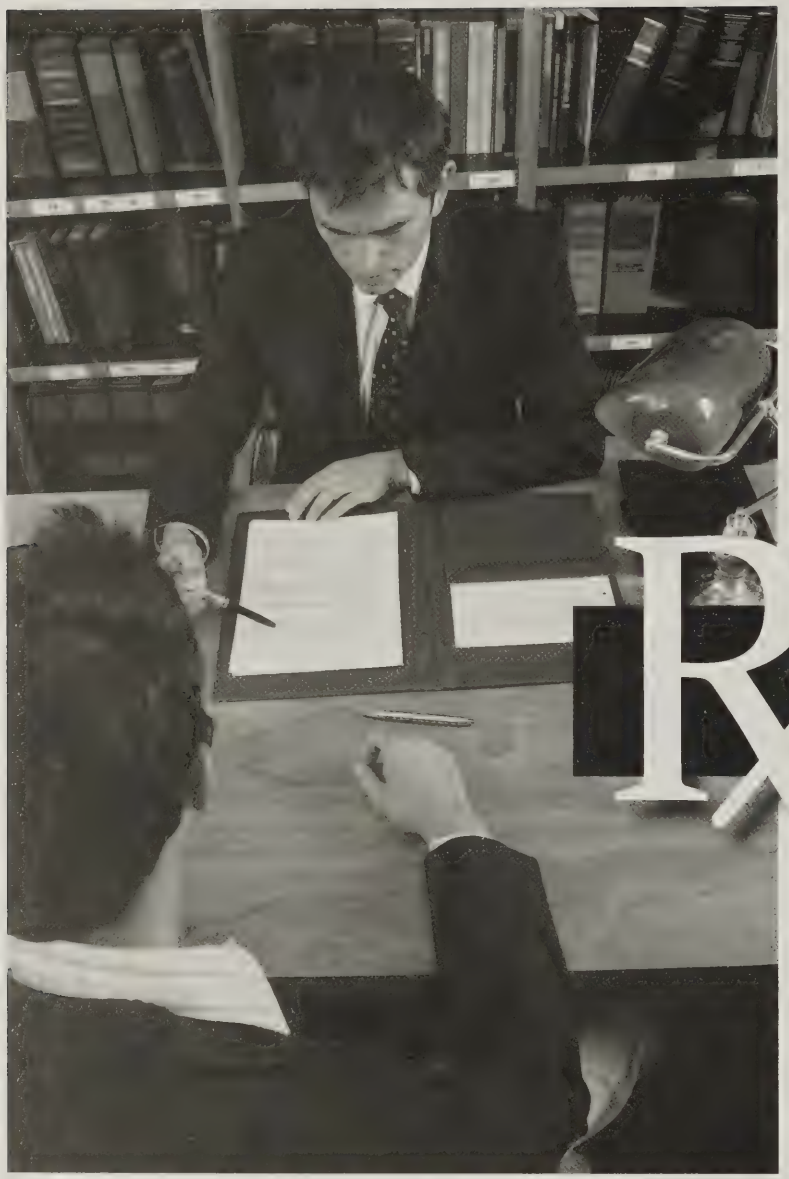

Rx AND THE LAW

By Don R McGuire Jr., RPh, JD

DISCOVERY 101

Ask anyone who works in the claims department at an insurance company and they will tell you that the Discovery phase of litigation is the most time-consuming and expensive part of the process. But if you don't work in the claims department or a law firm, could you readily explain what Discovery is and why it is so costly?

Discovery is defined by Rules 26 to 37 of the Federal Rules of Civil Procedure[1]. Discovery is a process where opposing sides in the litigation share information about the case with each other. This process is mandatory, although compliance with the rules is generally self-enforced by the parties. This sharing of information takes many forms and helps each side to evaluate the strengths and weaknesses of their case prior to trial. These forms include:

1. Depositions by Oral Examination
2. Depositions by Written Questions
3. Interrogatories to Parties
4. Producing Documents, Electronically Stored Information, and Tangible Things, or Entering onto Land, for Inspection and Other Purposes

This series, Pharmacy and the Law, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

5. Physical and Mental Examinations

6. Requests for Admissions.

Depositions, whether written or oral, are one of the largest cost drivers in the Discovery process. Little use of Depositions by Written Questions is seen in most cases, so I will concentrate on Deposition by Oral Examination. The main reason that this exchange consumes so much time and money is that virtually anyone connected with the case can be deposed. The parties, employees of the parties, fact witnesses, and expert witnesses can all be deposed. Depending on the complexity of the case, the deposition can be a half day, whole day, or potentially even multiple days. Coordinating witnesses', parties', and attorneys' schedules can be a nightmare. This is multiplied in multiple defendant cases or class action cases. Depositions are important because they give a preview of what a witness is going to say on the stand at trial. Witness testimony is crucial to evaluating a case. Preparation for a deposition, taking the deposition, and analysis of the answers are time consuming for your attorney. If the number of depositions are large, Discovery is well on its way to being the most expensive part of litigation. Interrogatories are written questions that can only be submitted to the opposing party. They cannot be used to gain information from witnesses or other non-parties. There is a limit to the number of Interrogatories that can be served on the opposition. Many times Interrogatories are used to gather background facts such as date of birth, address, work history, arrest records, etc. As with deposition questions, it is permissible to object to questions, but the objecting party must have a good faith basis to object beyond just not wanting to answer.

Producing Documents, Electronically Stored Information, and Tangible Things, or Entering onto Land, for Inspection and Other Purposes is comprised of 2 parts. The inspection of land and/or buildings occurs when relevant, but the bigger issue here is documents. In the not too distant past, this rule dealt almost exclusively with documents. Not so today. This rule encompasses not only paper documents, but e-documents, e-mail, spreadsheets, photos, drawings, and almost anything else that you can imagine. Recent changes to the rule require that electronic documents be produced electronically to preserve the metadata. Metadata and its implications are a topic of their own, but be aware that metadata can have a dramatic impact on the evidentiary value of the documents themselves. When the case involves a complex issue and/or a long running issue, it doesn't take too long these requests for production to take on a life (and an expense) of their own.

Parties may also request that the opposing party undergo a physical or mental examination. This is not automatic. The request must be approved by the court. The examination must be relevant to some issue in the case, so this cannot be requested without reason. This is usually used in situations where the party wants an independent opinion on, or verification of, the opposing party's condition.

The last form of Discovery is the Request for Admission. This is a written request to the opposing party asking them to admit the truth of some facts, application of the law to the facts, or the genuineness of documents. As you might have guessed by now, the item in question must be relevant to the case at hand. The responding party must admit as requested, deny, or object to the request. Making an admission under this rule renders the issue decided and the issue is not debated at trial. This rule has the potential to shorten a trial.

Discovery is a process where opposing sides in the litigation share information about the case with each other. It is one of the largest cost drivers in the Discovery process.

Discovery is self-governed by the parties and the rules provide deadlines for responding to the various forms of requests. Also, the parties cooperate to establish an overall schedule for Discovery to take place so that depositions, etc. are completed during a reasonable timeframe. Disputes about Discovery make their way in front of a judge. The judge can order the parties to participate in Discovery and can impose further sanctions, up to and including dismissal of the case, for failure to do so.

Discovery is a very important part of the litigation process, but it can be very time-consuming and expensive to comply with. This is especially true for the pharmacist defendant who has to take time away to be deposed or spend valuable time searching for and organizing records. Your attorney does realize the impact that Discovery has on your life, but your attorney also knows the potential downside for failure to comply.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.

[1] I will use the Federal rules for this article because they are consistent nationwide. Many states mimic them for their own rules, but you should make sure which approach your state takes.

February 9, 2014 • MPhA/MD-ASCP/MSHP/MPhS

Mid-Year Meeting

The 2014 Mid-Year Meeting, sponsored by PharmCon, was held for the first time at the Marriott Inn and Conference Center at the University of Maryland University College and gathered nearly 250 attendees. Thanks to the dedication and hard work from the four professional organizations (MPhA, MD-ASCP, MSHP, and MPhS) the event was a great success!

The day kicked off with breakfast, followed by the morning continuing education sessions. Lunch followed and attendees had the chance to meet with the many exhibitors who came out to support this event. The afternoon sessions included four tracks and attendees had the option to choose which programs to attend. The day ended with only a little bit of snow and a Happy Hour hosted by the Professional Development Committee, which had a great turn out! A very special thanks to all those who attended, our Mid-Year speakers who gave educational and insightful presentations, and our student volunteers from all three Schools of Pharmacy. We look forward to seeing everyone again at next year's meeting!

Photo 1
Jen Furst, Monica Healy and Danielle Keeley

Photo 2
Past Presidents, Joe DeMino and Joe Marrocco

Photo 3
Doug Campbell, James Ritchie and Walter Abel

Photo 4
Some of our student volunteers: Sara Ly, Kelsey Tyson, Jane Kim and Pilar Davila

Photo 5
It was a full house for the morning sessions.

Photo 6
Gil Cohen, Matt Shimoda and Murhl Flowers

Photo 7
New Practitioner Network Members: Chris Charles, Joan Phillips, Deanna Tran, Kate Lodowski, Ilana Volansky, Ashley Moody, Jen Furst, Chai Wang

Photo 8
Christina Haddad and Sylvia Okrzesik

PREVENTING ADVERSE DRUG EVENTS:

Defining the Problem and PROMOTING Action

Eric Isley
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School of Pharmacy

Stephanie Walters
PharmD Candidate 2014
University of Maryland School of Pharmacy

Jennifer Thomas, PharmD

Adverse drug events (ADEs) are harmful and potentially preventable incidents that put patients at a higher risk for longer hospital stays, increased medical costs, and even death. It is estimated that ADEs and preventable ADEs (pADEs) can cost a single hospital up to $8.4 million a year.[1] According to the Centers of Disease Control and Prevention (CDC), nearly 700,000 emergency room visits are caused by ADEs every year.[2] In response to this risk to patients and the growing healthcare costs, the Office of Disease Prevention and Health Promotion (ODPHP) and its Federal Interagency Workgroups (FIWs) drafted the *National Action Plan for Adverse Drug Event Prevention*.[3] This article focuses on summarizing the most recent hospital ADE data, as well as introducing the scope and domains of the *Action Plan*.

The Healthcare Cost and Utilization Project (HCUP) monitors hospital ADEs. Between 2004 and 2008, hospital ADEs increased by 52% (from 3.1% of all inpatient stays in 2004 to 4.7% of all stays in 2008). However it is unclear if this increase was due to increased events, better reporting, or both.[4,5] In 2011, HCUP assessed what proportion of hospitalized ADEs were present on admission (POA) versus those that were hospital acquired (HA).[6] Thousands of hospitals from 46 U.S. states participate in HCUP, however only 32 of those states report POA statistics. There were 20 million hospital discharges assessed for ADE origin from hospital stays in 2011. There were three times as many POA ADEs (388 per 10,000 hospital discharges) as HA (129 per 10,000 hospital discharges) ADEs. In previous HCUP reports, the ADE rates were described as percentages; later reports transitioned to using events per 10,000 discharges as a standard format to increase comparability with other ADE monitoring systems. Of the total 2011 ADEs, the most common specific causes were *C. difficile* infection due to antibiotic use, antineoplastic drugs, and steroid use. Opioids and anticoagulants were also in the top ten causes of any ADE.[6]

The HCUP Statistical Brief #164 presented data for the four most common ADEs that occurred in hospital inpatient stays during 2011.[7] It identified steroids, antibiotics, opiates and narcotics, and anticoagulants as the most common causes, with these four events occurring at a combined rate of 50.4 per 10,000 discharges (19.7 steroids, 12.9 antibiotics, 11.2 opiates and narcotics, 6.7 anticoagulants). Overall, the highest among the four were steroids; however, when examining the rates across age groups, elderly (patients over 65) were more likely to experience an ADE associated with anticoagulant use. Patients over the age of 65 had the highest rates of any ADE compared with younger patients. Thus, as one may expect, the Medicare population had the highest overall rate of ADEs compared to patients who had private insurance or Medicaid. In fact, the Medicaid population had the lowest rates. Furthermore, urban teaching hospitals and private not-for-profit hospitals had the greatest ADE rates of the various hospital settings. This study identified medications that continue to be major causes of ADEs, as well as identifying which patients in various settings are at the greatest risk of experiencing an ADE.[7]

According to the Centers of Disease Control and Prevention (CDC), nearly 700,000 emergency room visits are caused by adverse drug events every year.

The *National Action Plan for Adverse Drug Event Prevention* draft document stated goal is to align the efforts of federal agencies to nationally reduce harm caused to patients by ADEs with a focus on three medication categories: anticoagulants, agents for diabetes, and opioids. The aim of the *Action Plan* is to reduce the most common, clinically significant, preventable, and measurable ADEs.[3] Within its scope, the *Action Plan* addresses ADEs caused by high priority drug classes (anticoagulants, diabetic agents, and opioids) that occur in high-risk populations, such as the elderly. In order to reduce the harms caused by these medications, the *Action Plan* identifies and seeks to rectify gaps within federal agencies and to align their efforts in preventing ADEs. The *Action Plan* identified four areas of focus to reduce ADEs: Surveillance, Prevention, Incentives and Oversight, and Investigation. The surveillance goal is to coordinate the current federal surveillance resources that already exist in order to assess the rates of ADEs, focusing on ADEs with a known significant public impact. Efforts are currently underway to refine the existing surveillance systems.

Recommendations for prevention efforts include sharing of evidence based prevention tools among the interested federal agencies, as well as non-federal health care workers and consumers. An emphasis is placed on using root-cause analyses to identify latent determinants (those involving the patient or provider) of ADEs, as well as systemic and organizational factors that may contribute to ADEs. The Department of Health and Human Services (DHHS) has various regulatory capabilities that involve oversight and incentives that can be leveraged to help prevent ADEs. DHHS has within its power the ability to use regulatory oversight of healthcare provision, various financial incentives, and Medicare/Medicaid initiatives. Examples include requiring hospitals to meet federal health and safety standards in order to participate in Medicare programs, as well as value-

based purchasing financial incentives where financial reimbursement is used to promote improvements in the quality of care. Lastly, the fourth area of focus, investigation, is intended to identify and assess gaps in the current knowledge of ADE prevention and to identify future research to address these needs.

For over ten years anticoagulants continue to be one of the leading causes of hospitalized ADEs in the United States. The *Action Plan* has identified specific areas of improvement in the current surveillance strategies, such as distinguishing between minor and major adverse bleeding events, improving access to electronic health records with pharmacy and lab data, and improving capturing ADEs in transitions of care, as well as within nursing homes and community-dwelling individuals. The evidence-based prevention tools for each of the different levels of care can be found within the *Action Plan*. Two examples are the Institute for Safe Medication Practices' "Pathway for Medication Safety" toolkit for the hospital setting, and the National Quality Strategy Priorities' (NQSP) "Opportunities for Advancing Anticoagulant ADE Prevention Strategies/Tools" for outpatient settings. Further incentives and oversight for anticoagulation ADE prevention are needed in each of these three care settings: specifically creating anticoagulation stewardship for inpatient settings, amending payment barriers to ensure the uptake of "high-quality ADE prevention strategies" in the community, and fixing the barriers to interdisciplinary anticoagulation care in the nursing home. Through the utilization of these initiatives and further research, an improvement in safe anticoagulant use is hopeful.

With the large numbers of people living with diabetes and taking medications to treat it, hypoglycemia is an important ADE that occurs far too often and may be preventable. Comparing surveillance data for hypoglycemic events is difficult because definitions of hypoglycemia vary. The *Action Plan* suggests standardizing the definition and coding of hypoglycemic events when using national surveillance tools to improve consistent reporting. Using evidence-based recommendations from reputable organizations is warranted to help prevent hypoglycemic events. Examples include recommendations from the American Diabetes Association and the American Geriatric Society to individualize a patient's glycemic goals based on life expectancy and comorbid conditions. More aggressive treatment to reach strict glycemic goals may not improve outcomes and puts patients at greater risk of hypoglycemic events. Various opportunities exist to reduce hypoglycemic events through proper use of incentives and oversight. These may include utilizing health information technology to alert providers of a patient's risk for hypoglycemia and various mechanisms for monitoring events that occur. The *Action Plan* also suggests various research opportunities in this area, such as examining how comorbid conditions may affect hypoglycemia, identifying rates of severe hypoglycemia in ambulatory care settings, and describing the impact of quality measures on the rates of hypoglycemia.

Opioid overdoses, both in normal care and abuse/misuse, are one of the leading preventable ADEs and are considered a major public health issue in America. Some of the advancements in surveillance strategies recommended by the *Action Plan* include improving measures to better distinguish between opioid ADEs due to abuse versus normal care, promoting the increased use of prescription drug monitoring programs (PDMPs), and identifying the appropriate method of surveillance based on inpatient or outpatient settings. The NQSP's tools and resources for the safe management of opioid therapy are described and organized by the following categories: self-care/health care provider knowledge, patients and family engagement, promoting best practices in the community, and communication/care coordination. Further oversight is recommended in three different areas: quality measures based on value-based purchasing incentives, coverage of these services, and using payer data to identify the misuse/abuse of opioid medications. Areas for study for the prevention of opioid ADEs include: continued research to ensure the appropriateness/effectiveness of opioid prescribing guidelines, scrutiny of real-world practice versus recommended pain management, and examination of the clinical outcomes of PDMPS.

Adverse drug events greatly impact our patients' quality of life and our nation's healthcare cost. A concerted effort throughout all levels of care is needed to help prevent future adverse events, and the draft *National Action Plan for Adverse Drug Event Prevention* is an important resource in guiding this effort.

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UNDERSTANDING THE HIGH-TOUCH MODEL: Getting Acquainted with Specialty Pharmacy

DEFINING SPECIALTY PHARMACY

Community pharmacy, in its broadest application, can be defined by the roles played by the community pharmacist in the healthcare system. According to the World Health Organization (WHO), community pharmacists have a breadth of responsibilities including, but not limited to:[1]

- Processing and dispensing prescriptions in a timely manner;
- Monitoring patients for safe drug utilization;
- Clinical care of patients (i.e. integrating prescription history information, clarifying understanding of medications, medication counseling, etc.);
- Extemporaneous preparation and small-scale manufacturing (compounding) of medications;
- Responding to symptoms of minor ailments;
- Informing healthcare professionals; and
- General health promotion.

In the United States, community pharmacies are often the most accessible point of care in the healthcare system. Furthermore, community pharmacies are widely considered to be the frontline of patient care in pharmacy practice.

Specialty pharmacy has recently emerged as a subset of community pharmacy practice. According to the Specialty Pharmacy Association of America (SPAA), a specialty pharmacy is defined as "a unique category of professional pharmacy practice that incorporates a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions."[2] The specialty pharmacy model incorporates three elements of optimizing patient outcomes. The first element, commonly referred to as the *high-touch service model*, is designed to optimize therapy adherence.[2] The term *high-touch* refers to the increased hands-on approach that specialty pharmacies use with their patients and care teams in disease management. This involves services to expedite the start of therapy, promote adherence, and manage patient dosing, drug effectiveness, and drug appropriateness.[2] The second element, patient satisfaction, is critical for the successful partnership between a specialty pharmacy and the patient.[2] Satisfaction accrues from the efforts of specialty pharmacies to remove physical, logistical, and all other perceived barriers in a supportive partnership. The third element of specialty pharmacy is the specialty pharmacy standard of care.[2] This incorporates clinical, operational, and administrative services for the patient. Clinical services for the patient includes removing barriers to medication administration such as pharmacist access around-the-clock and regular, personalized regimen reassessments.[2] Operational services for the patient includes removing barriers to medication access by maintaining product inventory and rigorous storage and shipping standards.[2] Administrative services for the patient include removing financial barriers to medication procurement such as obtaining prior-authorizations and connecting patients with assistance programs.[2]

In general, specialty drugs can be classified in three sub-categories: 1) self-administered therapies, such as those for rheumatoid arthritis, psoriasis, and multiple sclerosis; 2) products injected or infused in an office or clinic setting including vaccines and treatments for various immune disorders; and 3) office- and clinic-administered chemotherapeutic agents.[3]

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LEARNING OBJECTIVES

After reading this article, the learner should be able to:

1. Evaluate the similarities and differences between a specialty and community pharmacy.
2. Identify at least four types of diseases commonly managed by specialty pharmacies.
3. Describe the advantages and disadvantages of specialty pharmacies.
4. Outline a plan to incorporate basic specialty pharmacy services into a pharmacy practice setting.
5. Explain the role of the pharmacist in a specialty pharmacy.

KEY WORDS

- specialty pharmacy
- community pharmacy
- pharmacy services
- high-touch model
- specialty medications

TABLE 1

Common specialty medications corresponding to the disease for which they are indicated.[10]

Antineoplastics	Anti-HIV	Rheumatoid Arthritis	Hepatitis C	Other*
Bevacizumab	Abacavir	Etanercept	Sofosbuvir	Mycophenolate[i]
Imatinib	Saquinavir	Adalimumab	Simeprevir	Cyclosporine[i]
Goserelin	Lamivudine	Abatacept	Peginterferon a-2a	Somatropin[ii]
Tretinoin	Ritonavir	Golimumab	Peginterferon a-2b	Interferon b-1a[iii]
Erlotinib	Efavirenz	Certolizumab Pegol	Ribavirin	Glatiramer[iii]
Leuprorelin	Nelfinavir	Infliximab	Telaprevir	Paricalcitol[iv]

*This category includes common specialty medications indicated to treat solid organ transplants[i], growth hormone diseases[ii], multiple sclerosis[iii], or endocrine disorders.[iv]

Examples of specialty medications are shown in Table 1. Recently, a guideline for defining a *specialty drug* has been adopted by one healthcare data company after ratification by numerous trade associations.[4] The guideline suggests that a drug must have five of the following eight characteristics to be considered *specialty:*

- Target and treat specific, mainly chronic, and often rare conditions;
- Initiated by a specialist;
- Typically not administered orally;
- Requires special handling;
- Involves unique distribution and administration channels;
- Costly, ranging from $6,000-$750,000 per year;
- Usage warrants high degrees of patient management; or
- Patients may require reimbursement assistance.

A specialty pharmacy operates differently from a community pharmacy. A specialty pharmacy has the ability to devote more time to manage a patient's specialty medication regimen.[2] Prior-authorizations, financial resources, and prescription refills will all be addressed before they become burdensome for the patient.[2] This is not always the case in community pharmacy practice.

Despite the differences in operational structure, community and specialty pharmacies share core values. Specialty pharmacies will often have 24/7 access to pharmacists or nurses.[2] While not all community pharmacies hold these extended hours, 24-hour community pharmacies exist in many of North America's major cities and suburban areas. They offer access to pharmacists and trained staff outside of normal business hours; a significant benefit for patients who are unable to access the healthcare system during normal hours. Furthermore, the patient is the center of the pharmacy care model in both high-touch specialty pharmacies and community practice settings. Medication decisions in both areas ultimately aim to benefit the patient's safety and financial commitment. Services commonly offered by community and specialty pharmacies are compared in Table 2 (See page 21.)

UNDERSTANDING THE ADVANTAGES AND DISADVANTAGES OF SPECIALTY PHARMACY

Specialty pharmacies offer care services that may not necessarily be provided by general community pharmacies. There is increased coordination of care and expert advocacy for the patient with minimal inconvenience in a specialty pharmacy practice. Though supportive data is sparse with this new area of practice, focusing on the patient produces a tailored approach to care that improves medication adherence.[5] A study evaluating clinical and economic outcomes of a transplant specialty pharmacy program for post-renal transplantation patients found that an advanced degree of intervention by a specialty pharmacy was associated with fewer readmissions, lower healthcare costs, and higher adherence rates.[5] In patients with many comorbidities and health that hangs in a delicate balance, adherence to their medications can be the difference between poor health outcomes and living a relatively healthy life.[6]

The pharmacy also benefits from offering specialty medications and services. As a business, specialty pharmacies thrive because specialty medications are profitable.[6] A successful pharmacy in this niche of practice has the potential to generate large revenue streams and profit margins from greater reimbursement per prescription. Pharmacists, technicians, and

supportive staff collaboration with the care team encourages efficiency, professionalism, and productivity. This supports a more effective workflow in the pharmacy to optimize financial gains.[3] As it currently stands, reimbursement rarely comes from services provided by specialty pharmacies. Nonetheless, by offering these services, patients that would benefit from this focused care are more likely to bring in their specialty prescriptions. More patients means generating more prescription reimbursement and when dispensing more expensive specialty medications, larger profits ensue in a specialty pharmacy practice.

Specialty pharmacies often connect their patients with supportive financial resources enabling patients to better afford their inherently expensive medications. However, there are times when medication costs may remain high for the patient, even after using discount services. Specialty medications also require special handling, administration, and often risk being wasted due to patients' frequently changing drug regimens.[6] These additional considerations introduce increased potential for medication usage and safety errors.

Specialty pharmacy is a potentially lucrative niche in the pharmacy industry. It is currently evolving but overall supports efforts to expand the roles of pharmacists. These roles are discussed later in this article.

IDENTIFYING A PATIENT ELIGIBLE FOR SPECIALTY PHARMACY

All patients who use specialty medications may not benefit from services provided by specialty pharmacies. In addition, all patients who might benefit from specialty pharmacy services may not be using specialty medications. While there is no widely accepted system to recognize a patient who might benefit from specialty pharmacy services, it can be hypothesized that the first element for finding a potential candidate is to identify a patient managing a chronic disease state. This would make a patient likely to benefit from the services offered by the high-touch model. Diseases managed by specialty pharmacies are generally chronic conditions where disease control is the goal, rather than a cure.[2] A pharmacist could assess the patient's ability to manage their condition by considering the following questions:

- How stable are the patient's conditions?
- How appropriate is the patient's medication regimen?
- How frequently are changes made to the regimen?
- How complex is the medication regimen?
- Is the patient using these medications appropriately?
- What is the cost and is the patient able to afford the medication regimen?

TABLE 2

This table identifies common pharmacy services and the settings where these services are consistently offered.[11]

Description of Services	Community	Specialty
Evaluating the patient's ability to adhere to medications	✓	✓
Identifying and managing adverse drug reactions and side effects	✓	✓
Tailoring a drug regimen to fit a patient's lifestyle	✓	✓
Scheduling one-on-one appointments between the pharmacist and patient to discuss medication therapy		✓
Proactively managing primary and secondary insurance to optimize coverage benefits		✓
Proactively managing formulary issues to optimize medication coverage		✓
Delivering medications to your home or work	✓	✓
Providing weekly telephone calls or home visits after initiation of therapy		✓
Offering health status assessments (blood pressure screenings, lab testing, etc.)	✓	✓
Providing therapeutic dose adjustment and therapeutic interchange alongside follow up calls after new or changed therapies (with collaborative protocol)	✓	

Certain pharmacy services are offered in both the community and specialty pharmacy practice setting. Others have been developed by and are more commonly offered by specialty pharmacies.

Personal CaRxe Pharmacy recently identified an increase in their sales of immunosuppressant medications, specifically that of tacrolimus and mycophenolate mofetil. In addition, they discovered that a community hospital a few blocks away houses a comprehensive transplant center, where several of their new patients come from with these prescriptions. Personal CaRxe Pharmacy learned of the new specialty pharmacy model being implemented to address the challenges and opportunities for this patient population. In doing so, they aimed to utilize this model to ensure effective transitions of care and to enhance refill retention rate. They performed the following in order to establish themselves as a new specialty pharmacy:

1. Collaborated with the community hospital's healthcare providers to assess their patient care needs after hospital discharge.
2. Allocated resources for a pharmacist and technician who will solely work on filling, educating, and following up with patients about their specialty medications.
3. Provided additional training for the pharmacist and technician assigned to this service to guarantee optimal patient care.
4. Organized a group of individuals to manage the financial aspects of their medication acquisition (i.e. prior authorizations and insurance coverage information).
5. Set-up an automatic refill reminder and medication delivery system to ensure patients always have their medications on-hand.

Patients experiencing difficulty managing their chronic condition, who are non-adherent to therapy, are often good preliminary candidates for specialty pharmacy use. The term *preliminary* is used because continued patient satisfaction throughout the relationship is necessary for the partnership with a specialty pharmacy to succeed.[2] The pharmacist should clearly describe the experience that a specialty pharmacy will provide and gauge the patient's comfort in this transition of care. Since the high-touch model emphasizes a more patient-centered approach, perceptions of nonmedical factors (i.e. medication cost, convenience, and access) and their effect on overall care are accounted for to determine if someone is a good candidate for specialty pharmacy use. Once established, a patient's satisfaction must be maintained throughout their experience for the partnership to flourish long-term.[2]

INCORPORATING SPECIALTY SERVICES INTO YOUR PRACTICE

The business models of a successful specialty pharmacy and community pharmacy are similar in the sense that both pharmacies are playing a central role between drug procurement and drug dispensing/administration.[7] Many community pharmacies offer services in common with specialty pharmacies such as medication delivery, patient monitoring, or offering health status assessments. Due to time constraints, potentially restricted pharmacy space, and high work volume that community pharmacies are known for, these services might not be executed as efficiently as in specialty pharmacies. With that in mind, proper planning will help incorporate specialty pharmacy services into any pharmacy practice, especially community settings.

Before offering basic low-cost specialty services, the infrastructure of the pharmacy will need to be assessed.[8] A specialty pharmacy will need:

- Ample cold storage;
- Trained pharmacists and staff;
- Data capturing and reporting systems;
- Medical claims billing systems;
- Coordination of infusion services;
- Reimbursement support; and/or
- 24-hour on-call pharmacist(s).

The business model of a successful specialty pharmacy requires that it plays a central role between drug procurement and drug dispensing/ administration.

In addition, staff training is important. The level of pharmaceutical care needed in a specialty pharmacy practice goes beyond the traditional dispensing, counseling process, and the community pharmacy needs to ensure that its staff meets certain requirements.[8] Staff should be trained to proactively obtain medication refills from prescribers, clear prior authorizations through insurance companies, and eliminate insurance discrepancies for patients. Ultimately, this makes for a smoother start because these are basic services offered by most specialty pharmacies. Pharmacy technicians may also obtain specialized training on common specialty drugs and handling/dispensing techniques.[2,3] This allows management to assess the pharmacy's current performance status and identify

future efforts required from their team toward implementing a specialty pharmacy program.

Additional specialized training for pharmacists may be necessary to establish a specialty program. While specialized pharmacist training is not required by law, numerous pharmacy associations encourage advanced specialized expertise by means of postgraduate residency, board certification, and/or specialty certification. The Specialty Pharmacy Certification Board (SPCB) has recently established a Certified Specialty Pharmacist (CSP) examination.[9] A nationally certified development process was used to create this objective tool for identifying competent professionals within specialty pharmacy.[9]

Other considerations include store design, customer service, clinical programs, and marketing. Analysis of these components might identify barriers for program development and influence methods for implementing specialty programs. Deciding which specializations and clinical programs the pharmacy wants to offer will help define a targeted patient population and engage marketing strategies. Implementing more complex specialty services (described in Table 2) could be considered as more patients requiring these services are involved.

RECOGNIZING THE ROLE OF THE PHARMACIST IN A SPECIALTY PHARMACY

In a specialty pharmacy, the pharmacist is responsible for integrating the clinical, administrative, and operational elements of specialty pharmacy into everyday practice.[2] By doing so, the high-touch specialty pharmacy service model can succeed in its aim to remove barriers to therapy adherence.[2]

While executing daily tasks in a specialty pharmacy is a team effort, the pharmacist is responsible for maintaining inventory of specialty medications, managing workflow, and remaining accessible to the patients. Given their accessibility, community pharmacists have the potential and responsibility to screen and recognize patients in need of specialty pharmacy services.

The pharmacist in a specialty pharmacy is also responsible for integrating the level of communication on which the business model is balanced. Patient care becomes comprehensive when the pharmacy, providers, and payors communicate frequently, efficiently and effectively.[7] The financial success of a specialty pharmacy is rooted in this high-touch model, offering enhanced communication alongside attractive services designed to improve patient outcomes. These attractive services aim to increase patient flow, prescription volume, and ultimately revenue for the business.

Integrated team decision making, efficient communication, and proactive financial management encompass the responsibilities of the pharmacist in promoting successful business practices and patient health.

SUMMARY

Specialty program development in a community pharmacy can pose many challenges. A particular challenge is that the pharmacist is responsible for assessing the infrastructure of the pharmacy prior to implementation—a skill not typically taught in school. Determining the physical, financial, and personnel status of the pharmacy is pivotal to outlining a structured growth plan for developing a specialty program.[8] It is also the responsibility of the pharmacist to possess and maintain advanced licenses and/or certifications; and to encourage the same for technicians and supportive staff.[6] However, the pharmacist who can overcome those challenges and establish a specialty pharmacy is a supportive source of expertise to many patients who can provide unparalleled high-quality service.

ACKNOWLEDGEMENTS

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Food for thought:

- How can a pharmacist prepare for the Certified Specialty Pharmacist (CSP) examination?
- How does developing a specialty pharmacy impact its surrounding community and already established local pharmacies?
- What start up costs should be accounted for in opening a specialty pharmacy?
- How do pharmacist-prescriber relations influence services in a specialty pharmacy?
- How might the high-touch model mature or change in years to come? How might it influence the whole industry in the future?

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AdvoCaring

Christine Meehan
PharmD Candidate 2014
Notre Dame of Maryland University School of Pharmacy

Throughout my nearly four years at Notre Dame of Maryland University School of Pharmacy (NDMU-SOP) I have had the honor of participating in the AdvoCaring Program. The AdvoCaring Program is a novel community outreach project developed by two extraordinary pharmacists and NDMU-SOP faculty, Dr. Nicole Culhane and Dr. Michelle Fritsch. This community outreach project was implemented as a way to give back to Baltimore by assisting underserved populations in the surrounding area. In the program, each student is assigned to an advising group that is paired up with a targeted, underserved population, which they will follow throughout their educational experience at NDMU. The program aims to give back to the community and to provide student pharmacists with a professional learning environment where they can practice their developing clinical skills to the benefit of the Baltimore community.

My advising group was matched up with Gilchrist Hospice Care located in Towson, Maryland, the largest hospice care organization in the state. Gilchrist provides inpatient as well as home-based quality care to thousands of patients and their families in the state of Maryland. Hospice care is defined as supportive or palliative care for individuals diagnosed with incurable illnesses. We were afforded the opportunity to perform annual needs assessments; promote health and wellness through blood pressure screenings, diabetes education, and medication safety at wellness fairs hosted for Gilchrist staff and patient's families; organize a flu clinic; and participate in fundraising events for Gilchrist's sister hospice center in Tanzania. The preceding list is not exhaustive; rather, it is a representative sample of the type of rewarding work students are able to experience in the AdvoCaring program.

One of my most memorable and rewarding experiences with the program was participating in the Adopt A Family for Thanksgiving in 2011. We were fortunate enough to get five Thanksgiving meals donated from Shoppers grocery store to provide families of Gilchrist home hospice patients with a full Thanksgiving meal. Eight student pharmacists, myself included, shopped for the items generously donated by the Shoppers in the Perring Plaza Shopping Center the day before Thanksgiving. Each meal consisted of a turkey; a can of yams, vegetables, and cranberry sauce; a bag of dinner rolls; and a pumpkin pie for dessert. We decorated cardboard boxes and wrapped up each meal to create a special gift for each family selected by the Gilchrist staff. Participating in the Adopt A Family for Thanksgiving event was a moving experience. Helping families that were unable to purchase a Thanksgiving meal—whether for financial reasons or the inability to leave their loved one at home for a period of time—was a humbling experience that has sparked my desire to continue to assist people in need.

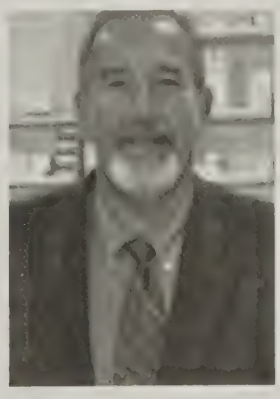
> "Through the AdvoCaring project, I have a new understanding of what a student pharmacist can accomplish and have developed an ever-growing compassion for helping people in need."

I sincerely believe that the initiation of the AdvoCaring project has touched many lives, including mine. I have had the opportunity to witness how donating a couple of hours to hospice each semester can have a positive impact on many lives. It was remarkable to learn that a "Pharmacy Call-List," which consisted of compiling a database of pharmacies in areas where home hospice patients lived who carried comfort medications, saved Gilchrist approximately four thousand dollars. I had no idea that as a student pharmacist I could make such a big impact. Knowing that I participated in giving five families, suffering through the impending loss of a loved one, a wonderful Thanksgiving meal brings a smile to my face. Through the AdvoCaring project, I have a new understanding of what a student pharmacist can accomplish and have developed an ever-growing compassion for helping people in need. My experiences with this project will stay with me forever and have already begun to impact my clinical decisions as a future pharmacist. I am eternally grateful for this experience and encourage other student pharmacists to develop connections with at-need populations in their area.

Members in the News

On January 27, 2014, **Peggy Funk**, Interim Executive Director, accepted the Maryland Pharmacists Association's 2013 Marketing Excellence Award for Best Non-Profit Campaign presented by the American Marketing Association Baltimore. The Marketing Excellence Award recognizes outstanding and effective marketing that demonstrates a campaign's success with measurable results in the Greater Baltimore region. This award focused on MPhA's integrated marketing and communications campaign that included the promotion and execution of all of the Association's initiatives surrounding membership recruitment and retention, social media programming, NPN, and inclusion of the new tagline "Stronger by Association."

Dr. Dennis Killian, PharmD, PhD, pharmacy director at Salisbury's Peninsula Regional Medical Center, has accepted an offer from the University of Maryland Eastern Shore School of Pharmacy to be the Interim Dean. Dr. Killian received his PharmD and PhD in pharmaceutical science from the University of Maryland School of Pharmacy. He also teaches at UMES in the areas of pharmacokinetics, pharmaceutical calculations and pharmacy automation.



Apple Discount Drugs, owner and president **Jeff Sherr**, was recognized by OutcomesMTM as a top pharmacy that has demonstrated a dedication to Medication Therapy Management and a commitment to improving the health of their patients. Apple Discount Drugs performed over 250 Comprehensive Medication Reviews in 2013. OutcomesMTM provides monthly updates in their national newsletter on Medication Therapy Management activities targeted toward pharmacy providers across the country.

The Maryland Chamber of Commerce announced **Ellen Yankellow**, president and CEO of Linthicum Heights-based CorrectRx Pharmacy Services, as an inductee into the 2014 Maryland Business Hall of Fame. She will be honored on May 6 during the Maryland Chamber's Annual Meeting & Business Hall of Fame Awards Dinner. Yankellow currently is Chair of the University of Maryland-School of Pharmacy Board of Visitors and serves on numerous other boards.

Bruce Anderson, PharmD, DABAT, was honored by University System of Maryland Board of Regents with a 2014 Faculty Award from the University of Maryland, Baltimore. Anderson was the regents' public service winner for his work as director of operations at the School of Pharmacy's Maryland Poison Center. Anderson is also an associate professor in the Department of Pharmacy Practice and Science at the School of Pharmacy.

Jill Morgan, PharmD, BCPS, was also honored by University System of Maryland Board of Regents with a 2014 Faculty Award from the University of Maryland, Baltimore. Morgan was recognized with the regent's award in mentoring. She is an associate professor in the Department of Pharmacy Practice and Science at the School of Pharmacy and its former associate dean for student affairs.

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RECOGNIZING EXCELLENCE
Kristen Fink

MANAGEMENT OF PAINFUL DIABETIC NEUROPATHY

Maryland Pharmacist

Collaborative Practice may sound intimidating, but you can do it! The Maryland Pharmacists Association and the Professional Development Committee are committed to assisting you with each and every step of the way.

Dear MPhA members,

Recently I was interviewed by three student pharmacists. One of the students asked me the following question, "What is unique about your position that would make a student want to have a similar career?" My answer was simple; I have two collaborative practice agreements with a physician's group; metabolic syndrome and anticoagulation. Physicians refer patients to me and I schedule visits with them either at the pharmacy or in the physicians' offices. I have the ability to adjust doses and make recommendations to therapy. The physicians are beginning to refer patients for Comprehensive Medication Reviews. The partnership that Fink's Pharmacy has developed and continues to grow has allowed me the opportunity to practice pharmacy in very innovative ways. Students ask me all the time how did Fink's Pharmacy start a collaborative practice with a physician. The answer is simple, we asked. The Finks identified physicians that they had developed strong relationships with and asked. Fink's Pharmacy is still the only community pharmacy in the state of Maryland with a Collaborative Practice Protocol in place. This year we want to change that. The MPhA Professional Development Committee, co-chaired by Kristen Fink and Hoai-An Truong, will be hosting a Collaborative Practice Webinar series beginning this year. Additionally, an article is scheduled to be published in the upcoming journal regarding compensation opportunities. Collaborative Practice may sound intimidating, but you can do it! The Maryland Pharmacists Association and the Professional Development Committee is committed to assisting you with each and every step of the way. Add Collaborative Practice to the top of your New Year's to-do list. If you have any questions about Fink's Pharmacy Collaborative Practice please feel free to contact me at cleerx@hotmail.com

Finally, following the weekend of the first Board of Trustees Meeting we kicked off Pharmacy Month with the Third Annual Medication Therapy Management Summit and what a tremendous success it was! Thank you to the Professional Development Committee for recruiting a program full of dynamic nationally known speakers. Many of which are members of MPhA including Nicki Brandt, Arnie Clayman, Ashley Moody, and Emily Pherson. Thank you to the staff and students who volunteered at the event making sure everything from start to finish ran smoothly. A special thank you goes to all the committees who donated a basket for the Foundation Raffle. The fundraiser was so much fun and we will be sure to do it again.

Warm regards,

Christine Lee-Wilson

Christine Lee-Wilson, PharmD
President

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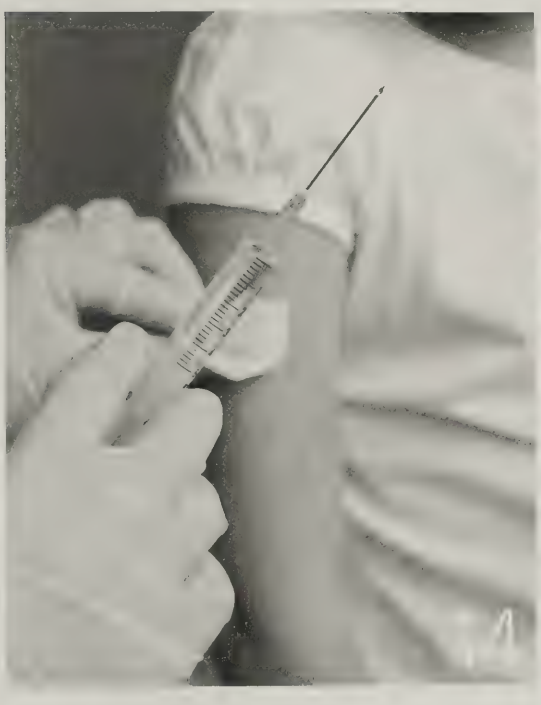

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A Glimpse into MPhA's New Practitioner Network (NPN)

Sara Ly, PharmD Candidate 2015, University of Maryland School of Pharmacy

The mission of the New Practitioner Network (NPN) is to provide a venue for new practitioners to network as well as exchange ideas and information to further professional development. By supporting the transition from student to pharmacist, the New Practitioner Network helps new graduates in Maryland by empowering them to become advocates for the future of their profession.

The New Practitioner Network provides activities and events targeting the needs and interests of new practitioners. The network is a great resource to gain support through a close-knit group of mentors and peers advocating for the profession of pharmacy. As described by P. Tim Rocafort, co-chair of the events sub-committee, "NPN has helped me connect with other practitioners in Maryland, share innovative patient care ideas, and also just kick back and relax after a long day at work." Furthermore, NPN can help ease new practitioners into professional life and serve as an outlet to Maryland pharmacy outreach.

Currently, the NPN serves over 200 new practitioners in the state of Maryland with over 75 of them working in the NPN committee! New practitioners are defined as any pharmacist who has graduated within the past five years and currently includes graduates from the classes of 2009-2013. The NPN is an added benefit of Maryland Pharmacists Association's membership and is provided at no additional cost.

Having recently celebrated the first year anniversary of the New Practitioner Network in December 2013, NPN members are fired up about the future growth of the committee. Deanna Tran, co-chair of NPN states, "We are so excited that NPN has taken off in its first year. We hope future networking, social, and professional development events targeted specifically for new practitioners brings increased involvement and fun times for everyone!"

> "I believe the future of NPN is in bridging the divide among pharmacy professionals, especially as the role of pharmacists continue to evolve at a rate greater then ever seen before."
>
> — *Scott Morrissey*

With the New Year coming into full swing, NPN members have been working hard to be able to offer an exciting array of upcoming events for new practitioners across different career paths in pharmacy. This includes unique opportunities at MPhA's Annual Convention, Mid-Year Meeting, and Medication Therapy Management

Continued on page 6

Recent events that have been hosted by the NPN

"Keep Calm and Network On"

Networking event for students and new practitioners at MPhA Annual Convention 2013

"Step Out: Walk to Stop Diabetes"

MPhA sponsored a team of pharmacists and student pharmacists, raising over $500 to help fight to find a cure for diabetes

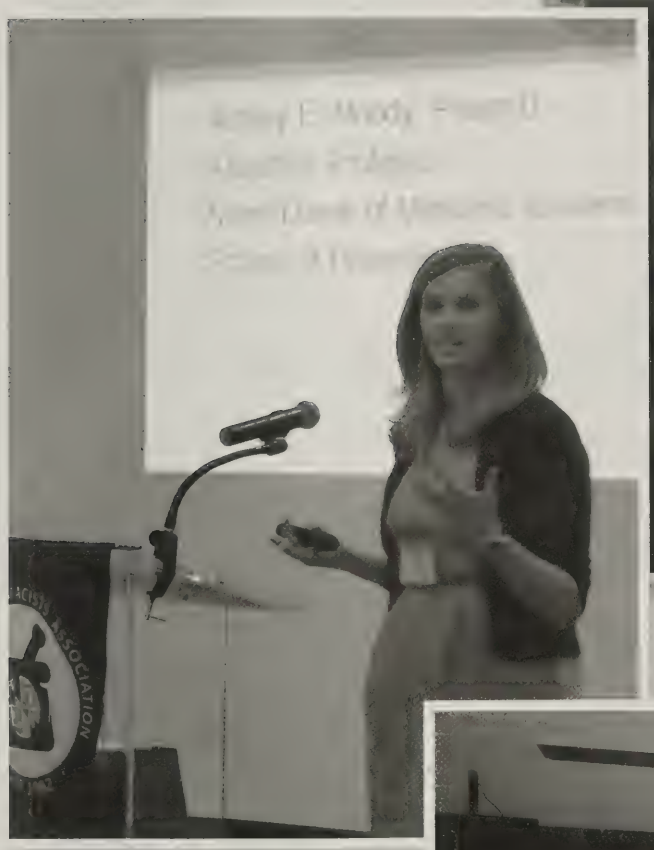
Continuing Education Presentations

Presented at the MPhA Annual Convention and MPhA/MD-ASCP Mid-Year Meeting 2013 given by and targeting new practitioners

Monthly NPN Happy Hour

First Happy Hour event at Nick's Fish House and Grill attended by 17 new practitioners and students for a relaxing evening of mingling and networking

New Practitioner Emily Pherson presents MTM Pearl: "Post-Discharge Pharmacist-Provided Home-Based Medication Management Pilot" at MPhA's Third Annual MTM Summit



New Practitioner Ashley Moody presents MTM Pearl: "View Through the Magnifying Glass of Establishing Community Pharmacy Based MTM Services" at MPhA's Third Annual MTM Summit

NPN members enjoying "Strike Out with NPN" bowling social

A Glimpse into MPhA's New Practitioner Network

continued

Summit hosted by MPhA. In addition, NPN is planning various personal and professional development activities for new practitioners and students such as a Financial Planning Crash Course. When asked about the future of NPN, member Scott Morrissey expressed, "I believe the future of NPN is in bridging the divide among pharmacy professionals, especially as the role of pharmacists continue to evolve at a rate greater then ever seen before." Another goal for 2014 is to optimize the usage of interactive social media and use it as an adjunct to help build stronger connections within our network of Maryland new practitioners.

While any practitioner that has been in practice for five years or less and student pharmacists in their third or fourth year are eligible to attend NPN events, the committee is also seeking enthusiastic individuals looking for opportunities to get involved professionally early-on and shape their burgeoning career. The New Practitioner Network holds monthly committee meetings open to all members to discuss and devise action plans for upcoming events. "We are always brainstorming and thinking of new ways to have our ideas heard," states Kristen Dominik, co-chair of the events sub-committee. Since its recent launch the NPN committee has made significant strides in developing a solid infrastructure to support the growth and development of NPN. The operational efforts of NPN are split into the following three sub-committees:

- Public Relations: The Public Relations sub-committee's mission is to expand the professional scope of NPN by strategically relaying information to target the audience of pharmacists and student pharmacists. The sub-committee strives to build invaluable relationships by increasing participation in NPN hosted events that will further the growth of its membership.
- Events: The Events sub-committee aids the transition of student pharmacists into new practitioners in Maryland. This is accomplished by providing an avenue for new practitioners and seasoned pharmacists to network and exchange ideas while engaging in community service activities and social excursions.
- Programming: The Programming sub-committee coordinates and plans professional development events, such as CE presentations and student-specific programming that help new practitioners grow both personally and professionally, as well as keep an edge on their practice.

Involvement with any one of the NPN sub-committees offers many leadership opportunities and the chance to implement innovative ideas, and access to a support network. More information on NPN and how to become involved can be found on the MPhA website (marylandpharmacist.org), or by contacting either of NPN's committee co-chairs:

- Deanna Tran – tran.deanna@gmail.com
- Ashley Moody – mccabe.ashley@gmail.com

New Practitioners and students at Nick's Fish House and Grill enjoying the first monthly NPN Happy Hour

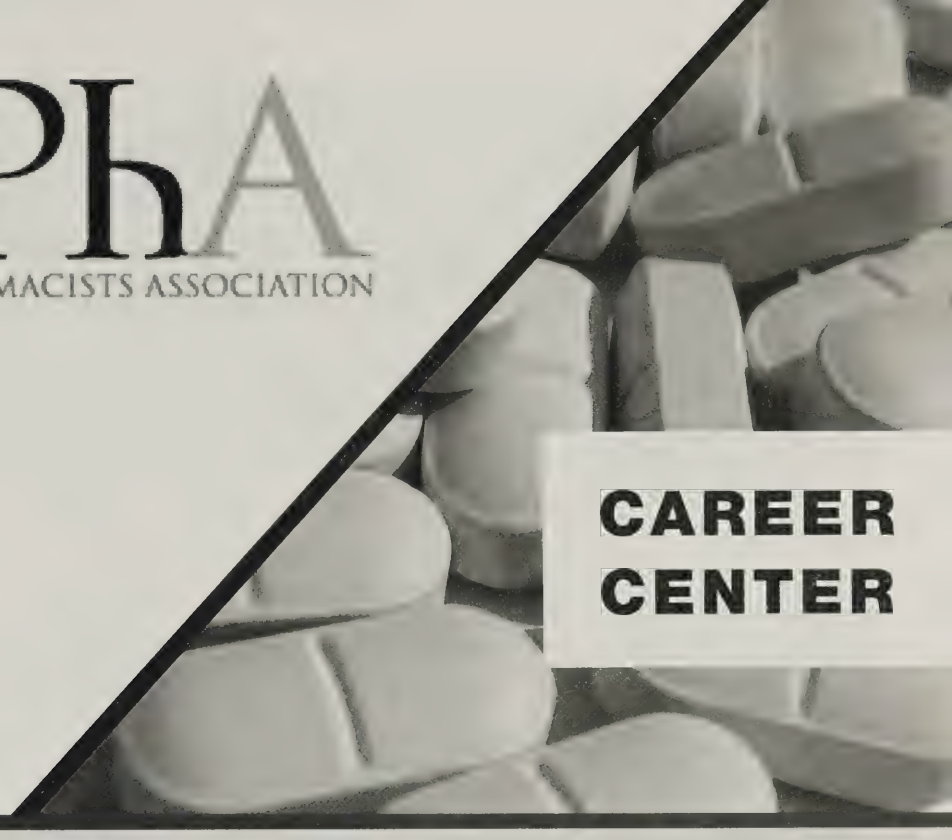
Top row (left to right): Lauren Lakdawala, Tim Rocafort, Chris Charles, Kristen Dominik, Jamie Elsner, Dave Goffman

Middle row (left to right): Lubna Kousa, Linda Quach, Ashley Moody, Susan Pajak

Bottom row (left to right): Ashley Pham, Deanna Tran

MPhA

MARYLAND PHARMACISTS ASSOCIATION



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Welcome to our *newest* members!

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Emily Dvorsky
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Isiah M Harper
Cassandra Jakubowski
Lauretta Kerr
Nicholas Ladikos
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James Santford Williams
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Entrepreneur of the Year Named

Magaly Rodriguez de Bittner

Magaly Rodriguez de Bittner, professor and chair of the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy, has been selected as the University of Maryland, Baltimore's Entrepreneur of the Year. Dr. Bittner has lead the implementation of nationally-recognized programs, such as the Maryland P3 Program and consistently demonstrates the role of a professional in her field. She is the first women ever to receive this award.

American Association of Colleges of Pharmacy Selects President-Elect

Cynthia J. Boyle, MPhA past President and former Foundation President, has been selected to be the new president-elect of the American Association of Colleges of Pharmacy. She finished her term as Speaker of the House for AACP this past July and will assume its top office in mid-2015 after serving the next academic year as president-elect.

Cynthia Boyle

Patient Safety Pharmacy Collaborative Award Recipient

For the second year in a row, **Jennifer Thomas** has been selected as the Patient Safety Pharmacy Collaborative (PSPC) Award recipient for the Quality Improvement Organization Partner Award. This award recognizes an individual/organization within the QIO community that has adopted the PSPC culture and works tirelessly to support all teams within and/or outside their region. Due to Jennifer's vigorous efforts, she has increased the number of active PSPC teams from one to seven in Maryland and the District of Columbia.

Jennifer Thomas

The College of Psychiatric and Neurologic Pharmacists Elects President-Elect

The College of Psychiatric and Neurologic Pharmacists (CPNP) membership has elected **Dr. Raymond Love** to serve as President-Elect on the 2014-2016 Board of Directors. Dr. Love is also currently serving as Member at Large to the Board. CPNP is a professional association of over 1,100 members dedicated to promoting excellence in pharmacy practice, education and research to optimize treatment outcomes of individuals affected by psychiatric and neurologic disorders.

Raymond Love

2014 Community Pharmacy Residency Excellence in Precepting Award Recipient

Cherokee Layson-Wolf, PharmD, associate dean for student affairs and associate professor of pharmacy practice and science, has been selected to receive the American Pharmacists Association's 2014 Community Pharmacy Residency Excellence in Precepting Award.

Cherokee Layson-Wolf

CORRECTION

In the Fall 2013 issue of *Maryland Pharmacist*, Sajal Roy's name was misspelled. Dr. Roy is the newest appointee to the Board of Pharmacy appointed by Governor Martin O'Malley.

2014 Maryland Pharmacists Association Awards

Recognizing Pharmacy Excellence

Each year, MPhA recognizes individual professional excellence during the Annual MPhA Convention held in Ocean City, MD. To nominate a deserving pharmacist for one of the awards described below, complete and submit the nomination form below to: Award Nominations, c/o Maryland Pharmacists Association, 1800 Washington Blvd., Suite 333, Baltimore, Maryland 21230-1701. Nominations can also be submitted online at marylandpharmacist.org. **For consideration, nomination forms must be received no later than Friday, March 28, 2014.**

Nominations are reviewed and selections made by the Past Presidents Council. Upon selection, individuals will be notified in advance of the Annual Convention.

Bowl of Hygeia Award sponsored by the American Pharmacists Association Foundation and National Alliance of State Pharmacy Associations Boehringer Ingelheim – Premier Supporter

Established in 1958, the Bowl of Hygeia Award recognizes pharmacists who possess outstanding records of civic leadership in their communities and encourages pharmacists to take active roles in their communities. In addition to service through their local, state, and national pharmacy associations, award recipients devote their time, talent, and resources to a wide variety of causes and community service. Any MPhA member pharmacist who has not already received the Bowl of Hygeia Award is eligible for nomination.

The Bowl of Hygeia is the most widely recognized international symbol for the pharmacy profession and is considered one of the professions most prestigious awards. The Bowl of Hygeia has been associated with the pharmacy profession since as early as 1796, when the symbol was used on a coin minted for the Parisian Society of Pharmacy. The bowl represents a medicinal potion and the snake represents healing.

Understanding the value of the Bowl of Hygeia to the profession of pharmacy, and the need for the managing organizations to focus on fundraising for an endowment, Boehringer Ingelheim stepped in to become the Premier Supporter of the Bowl of Hygeia program in 2012. This allows the base funds that have been previously donated to stay intact while an endowment fundraising program continues.

Maryland Pharmacists Association Seidman Distinguished Achievement Award

Created by Henry Seidman, this award honors a Maryland pharmacist who has performed outstanding service over a number of years, and whose service has resulted in a major impact on the pharmacy profession. MPhA pharmacist member who meet the criteria for this award are eligible for nomination.

Excellence in Innovation Award sponsored by Upshire-Smith Laboratories, Inc.

Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing MPhA pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care is eligible for nomination.

Distinguished Young Pharmacist Award sponsored by Pharmacists Mutual Companies

This award is presented each year to a pharmacist who has graduated within the past ten years and has made a significant contribution to the profession through service to a local, state, or national pharmacy organization. Any MPhA pharmacist member who has graduated from a school of pharmacy within the last ten years is eligible for nomination.

Maryland Pharmacists Association Mentor Award

This award recognizes individuals who encourage pharmacists, technicians, and/or student pharmacists in the pursuit of excellence in education, pharmacy practice, service, and/or advocacy. Any MPhA pharmacist member who meets the criteria for the award is eligible for nomination.

Cardinal Health Generation Rx Champions Award sponsored by Cardinal Health Foundation

This award honors a pharmacist who has demonstrated outstanding commitment to raising awareness of the dangers of prescription drug abuse among the general public and among the pharmacy community. Any MPhA pharmacist member who meets the criteria for the award is eligible for nomination.

Maryland Pharmacists Association Honorary President

An honorary position on the Board of Trustees is given to a person, not necessarily a pharmacist, who has worked for MPhA or Maryland Pharmacy over a long period of time. Any long standing contributor to the profession or the Association is eligible for nomination.

Award Nomination Form

To nominate an individual for one of MPhA's annual Recognizing Pharmacy Excellence awards, complete and return this form to Award Nominations, C/O Maryland Pharmacists Association, 1800 Washington Blvd., Suite 333, Baltimore, MD 21230, no later than Friday, March 28, 2014. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please provide the information as requested for each nominee and attach a current resume or a curriculum vita that demonstrates their professional and personal achievements. This information is essential for the Past Presidents Council to make well-informed decision as to which candidates will be selected. Also please include a brief statement explaining why the nominee is deserving of the award. **If you would prefer to make your nomination online, visit marylandpharmacist.org.**

Bowl of Hygeia Award sponsored by the American Pharmacists Association Foundation and National Alliance of State Pharmacy Associations

Nominee

Address

City/State/Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

Maryland Pharmacists Association Seidman Distinguished Achievement Award Association

Nominee

Address

City/State/Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

Excellence in Innovation Award sponsored by Upshire-Smith Laboratories, Inc.

Nominee

Address

City/State/Zip

Daytime Phone

Employment/Practice

Nominated by

Phone

Distinguished Young Pharmacist Award sponsored by Pharmacists Mutual Companies

Nominee

Address

City/State/Zip

Daytime Phone

Employment/Practice

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Phone

Maryland Pharmacists Association Mentor Award

Nominee

Address

City/State/Zip

Daytime Phone

Employment/Practice

Nominated by

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Cardinal Health Generation Rx Champions Award sponsored by Cardinal Health Foundation

Nominee

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2013 Recipients of the "Bowl of Hygeia" Award


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Arizona


Karrol Fowlkes
Arkansas*


Vicki Fowlkes
Arkansas*


Helen K Park
California


Ronald Kennedy
Colorado


Gregory L Hancock
Connecticut


David W. Dryden
Delaware


Judith Martin Riffee
Florida


William Lee Prather
Georgia


Selma Yamamoto
Hawaii


Mark Johnston
Idaho


Garry Moreland
Illinois


Patrick Cashen
Indiana


Bernard Cremers
Iowa


Leland Hanson
Kansas


J Leon Claywell
Kentucky


Douglas Boudreaux
Louisiana


Paul Chace
Maine


Angelo C. Voxakis
Maryland


John R Reynolds
Massachusetts


Nancy J W Lewis
Michigan


Harvey Buchholz
Minnesota


Clarence DuBose
Mississippi


Kenneth W. Schafermeyer
Missouri


Carla Cobb
Montana


Scott E Mambourg
Nevada


Cheryl A Abel
New Hampshire


Eileen Fishman
New Jersey


Phil Griego
New Mexico


James R. Schiffer
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Oklahoma


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Edward Bechtel
Pennsylvania


Daniel Mahiques-Nieves
Puerto Rico

Linda A Carver
Rhode Island

Linda Reid
South Carolina

Ann M Cruse
South Dakota

Kenneth Smith
Tennessee

Leticia Van de Putte
Texas

Dominic DeRose
Utah

Leo H Ross
Virginia

Janet Kusler
Washington

Russell Jensen
Wisconsin

Timothy Seeley
Wyoming

The Bowl of Hygeia award program was originally developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community. We offer our congratulations and thanks for their high example. The American Pharmacists Association Foundation, the National Alliance of State Pharmacy Associations and the state pharmacy associations have assumed responsibility for continuing this prestigious recognition program. All former recipients are encouraged to maintain their linkage to the Bowl of Hygeia by emailing current contact information to awards@naspa.us. The Bowl of Hygeia is on display in the APhA Awards Gallery located in Washington, DC.

Boehringer Ingelheim is proud to be the Premier Supporter of the Bowl of Hygeia program.

*husband and wife co-recipients

New Vaccinations Approved for the 2013–2014 Season

A closer look into the new influenza vaccinations and the expanded recommendation for the pneumococcal vaccination, PCV13 (Prevnar 13).

Hana Kim, PharmD, PGY-1 Resident,
Kaiser Permanente of the Mid-Atlantic States

With the flu season approaching, pharmacists can anticipate an influx of influenza vaccinations, as well as pneumococcal vaccinations. It is important to always stay up to date with any new vaccines or updated recommendations. For the 2013–2014 season, five new influenza vaccines were introduced, in addition to an expansion of recommendations of the pneumococcal vaccination (Prevnar13).

Flu seasons can be unpredictable in terms of the influenza strain and severity. The Centers for Disease Control anticipates possible strains yearly in order to develop the season's influenza vaccinations. Previously, trivalent vaccinations have been available on the market. Trivalent influenza vaccines contain three different strains of the influenza virus, protecting against two influenza A viruses and one influenza B virus. This year, a quadrivalent vaccination was formulated to protect against four strains, two influenza A and two influenza B viruses.

With the flu season aproaching, pharmacists can anticipate an influx of influenza vaccinations.

Five new vaccines have been approved and are marketed for this season: FluMist Quadrivalent, Fluarix Quadrivalent, Fluzone Quadrivalent, Flucelvax, and Flublok. Table 1 describes the new vaccinations available. Flucelvax and Flublok are manufactured in a manner that does not rely on using egg proteins, which may offer an option to patients with an anaphylactic egg allergy. Flucelvax may still contain very small, immeasurable amounts of egg protein. Flucelvax has not been directly studied in patients with egg allergies.[7] Flublok is the only vaccine available that does not contain any egg protein. It is also still important to consider the risk of using a live vaccine in patients who are pregnant or immunocompromised.

In addition to the new influenza vaccines, a new pneumococcal vaccine has been introduced this year. Current guidelines recommend the 23-valent polysaccharide vaccine (PPVSV23), Pneumovax, for adults older than 65 years of age and for those who are 2 years of age and older at high risk for disease. It is also recommended for adults 19–64 years of age who smoke or have asthma. The newer agent, pneumococcal conjugate vaccine 13, PCV 13 (Prevnar 13), was approved in 2010 only for use in children. In 2011, the vaccine was approved for those older than 50 years of age. In June 2013, the CDC's

Table 1 • New Influenza Vaccinations Available for the 2013–2014 Season

VACCINATION	FORMULATION	APPROVED FOR	DOSE	CONTRAINDICATIONS	PREGNANCY
FluMist Quadrivalent[1] Live attenuated, quadrivalent	Nasal spray	2–49 years of age	• 2-8 years of age: one or two doses,* 0.2 mL each • 9–49 years of age: 1 dose, 0.2 mL	• History of severe allergic reaction to any component of the vaccine (including egg product), or following a previous dose of any influenza vaccine • Concomitant aspirin therapy in children and adolescents	Pregnancy Category: B Safety and efficacy not established in pregnant or nursing women
Fluarix Quadrivalent[2] Inactivated, quadrivalent	Intramuscular (IM) injection	3 years of age and older	• 3–8 years of age: one or two doses* (0.5 mL, each)	• History of severe allergic reaction to any component of the vaccine (including egg product), or following a previous dose of any influenza vaccine	Pregnancy Category: B Safety and efficacy not established in pregnant or nursing women
Fluzone Quadrivalent[3] Inactivated, quadrivalent	IM injection	6 months of age and older	• 6–35 months of age: one or two doses* (0.25 mL, each) • 36 months to 8 years of age: one or two doses* (0.5 mL, each) • 9 years of age and older: one dose (0.5 mL)	• History of severe allergic reaction to any component of the vaccine (including egg product), or following a previous dose of any influenza vaccine	Pregnancy Category: C Safety and efficacy not established in pregnant or nursing women
Flucelvax[4] Recombinant hemagglutinin	IM injection	18 years of age and older	Single 0.5 mL injection	• History of severe allergic reaction to any component of the vaccine (including egg product), or following a previous dose of any influenza vaccine	Pregnancy Category: B Safety and efficacy not established in nursing women

**If 2 doses, administer 1 month apart*

Advisory Committee on Immunization Practices (ACIP) expanded the recommendation of PCV13 to adults equal to or older than 19 years of age who have immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants.[8] In addition, those who are naïve to pneumococcal vaccine within the previously mentioned patient population should receive a dose of PCV13 first, then a dose of PPSV23 at least 8 weeks later.[8]

When considering coadministering the pneumococcal and influenza vaccination, keep in mind the timing of administration of both vaccines. It has been reported that the inactivated influenza and PCV13 may cause a diminished antibody response to PCV13.[9] It is recommended to separate doses by approximately one month.

Pharmacist-administered vaccinations is one way we can offer quality patient care.

With the new influenza vaccinations and updated recommendations for the PCV13 vaccination, it is important to consider patient characteristics. For example, always keep in mind pregnant or nursing patients and the patient's age. Specifically, these two factors can change the recommendation for the type and timing of vaccinations. As pharmacists, we play an integral role in patient care, and pharmacist-administered vaccinations is one way we can offer quality patient care.

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RECOGNIZING Excellence

Kristen Fink

Cynthia J. Boyle, PharmD, FAPhA, FNAP
Professor and Chair, Department of Pharmacy Practice and Administration
School of Pharmacy, University of Maryland Eastern Shore

The annual Maryland Pharmacists Association awards luncheon is a highlight of the June convention, but if you were not able to attend, you may have only read the names of the honorees. This Member Spotlight article is one in a series that will feature award winners and distinctive members. The first featured award winner is Kristen Fink, recipient of the 2012 MPhA Excellence in Innovation Award.

AWARD BACKGROUND

Established in 1993, this award (formerly known as the Innovative Pharmacy Practice Award) aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing MPhA pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care is eligible for nomination. The Excellence in Innovation Award is decided by the MPhA Past Presidents' Council and supported with a stipend from the MPhA Foundation.

RECIPIENT BACKGROUND

Kristen Fink, PharmD, BCPS, CDE, graduated from Duquesne University in 2004 and completed a Managed Care Pharmacy Practice Residency at Kaiser Permanente. Dr. Fink is currently the Director of the Post Graduate Year 1 (PGY1) Residency Program at Kaiser Permanente, and Clinical Pharmacy Specialist specializing in outpatient primary care. She also educates, monitors, and manages medications for diabetic patients at Fink's Pharmacy, her family's independent pharmacy in Essex, Maryland. As the first independent pharmacist in the State of Maryland to practice drug therapy management under an approved Collaborative Practice Agreement, Dr. Fink collaborates with her physician partners to help care for their diabetic patients.

Kristen Fink serves as a trustee for MPhA and as co-chair of the Professional Development Committee for the past seven years.

Former Past President Neil Leikach with Kristen Fink

Q&A with Dr. Fink

What were your thoughts when you heard you would be recognized with the MPhA Excellence in Innovation Award?

What an honor to even be nominated for such an award. It is exciting to embark on a new adventure and develop a new practice. I was thrilled to be able to do it, hopefully paving the way for other pharmacists to begin collaborative practices.

What were the most important steps toward your innovative practice?

First I needed to demonstrate the value I could add to diabetes management of our patients. Since this was a new practice model for the first physician with whom I partnered, I was excited to show him how I could educate patients and monitor and adjust their medications to achieve quality goals. He gave me his most difficult and resistant patients at first. As they started working with me and coming back to their next physician visit with significantly improved symptoms and lab results, he could see the results immediately.

What was the major barrier for your innovative practice?

Initially it was sunset for the law allowing collaborative practice within the State of Maryland. The hard-fought opportunity for collaborative practice was due to expire. Once that was resolved through advocacy, it was simply the misunderstanding of our practice by the Board of Physicians, along with their hesitance to renew our agreement in a timely manner. We had a second group of physicians who had heard about how we could help with diabetes management. They were waiting to get involved, but without Board approval, we were stuck treading water. Luckily, after testifying to the Board of Physicians along with my physician partners, that issue has now been resolved, and the regulations have been re-written to avoid this barrier for us and other Maryland pharmacists in the future.

What will it to take for your innovation to become a standard of practice?

The will of the pharmacists! We are fully capable of working within collaborative agreements to modify and optimize medication therapies. Our education and training is specifically in the area of medication management, so who knows the ins and outs of the medication management better than we do?!?! We also need to figure out the reimbursement piece of the equation. The tremendous value of pharmacists through cognitive services has been proven again and again in all different practice settings. But insurance is still lagging in that pharmacists' reimbursement is tied to the product. Hopefully this will change as pharmacists obtain provider status.

How were you able to use the award stipend from the MPhA Foundation?

The stipend was a fantastic kick-start for new equipment in our everyday practice. It was also used for a database to help prove our outcomes. We spent some for the application fee to apply for American Association of Diabetic Educators (AADE) accreditation for our group education series. Hopefully that seed money will turn into real reimbursement funds for our educational efforts with the accreditation.

It takes knowledge, skills, and abilities to innovate. To what do you attribute your success?

I have been fortunate to have had training in starting a new clinic. I know that building the relationships is the most important part. Fortunately for me, my father has excellent relationships with many physicians throughout the Essex area, so it was easier for me to build off of those relationships to start this practice. I have always believed that I can accomplish anything that I put my mind to, so it never crossed my mind that we would not succeed. After that it was a matter of adjusting to challenges, and persevering to accomplish the goal.

You are a Dusquesne grad. What advice do you have for student pharmacists at your alma mater or in Maryland?

Believe in yourself and your abilities. Know that you have the training to be a great pharmacist and master any part of the field. Find the part of the profession that you have passion for, and pursue it with everything that you have. With that mindset, each day you go to work will not feel merely like a job. It will become your career and calling.

How are you able to serve as a trustee of MPhA, an innovative pharmacist, and a wife and mother? What does work-life balance look like?

My first thought was, "What work-life balance?" It all blends into one for me! In all honesty, I have been "accused" of living and breathing pharmacy, but it is in my blood and I love it. I love seeing our profession change, grow, and take on new challenges. When I took the BCPS exam, I told my husband that I would take a break after it was over. He knew I would find something new to tackle by the next week - and he was right! I am extremely fortunate that Andrew is so supportive, and we always put a high priority on having fun too —

taking the time out to travel, trying different restaurants, and embarking on new adventures. We just had our son, Ethan. He is 3.5 months old now, and he has definitely changed my perspective. I have to say that my biggest hobby is just watching him laugh and discover new things for the first time. Who knows? Maybe he will love pharmacy too and continue the family tradition!

How have your leadership skills developed as a volunteer leader?

I enjoy teaching and providing opportunities to others. I motivate people through role modeling. For example for the residency program, I like to organize weekly calls and give others the chance to volunteer for what they want to do. In other words, I match their talents with the tasks. We create short deadlines with regular follow-ups. I give people equal preference and don't shoot down ideas. The same works for the Professional Development Committee which continues to grow.

How do your colleagues describe you?

I am not sure. I would hope they think I am positive, up-beat, hard-working and dedicated.

What does MPhA membership mean to you?

MPhA has been wonderful for me. When I first moved back to the state, MPhA was the place that I went to find out what was happening in the pharmacy world in Maryland. I was welcomed with open arms. I have always found MPhA to be a very welcoming and upbeat organization. Members like to collaborate and support anyone trying to grow the profession - and they have fun in Ocean City during the annual convention!

What does your pharmacy future look like?

I am not sure. When my term as trustee is over, I know I want to be involved. Maybe I will work through the MPhA Foundation or the Maryland Board of Pharmacy. I am optimistic about our profession. If pharmacists take that first step, we can go far. We can all do collaborative practice and patient care. Patients face many chronic conditions. We need to step up and help them.

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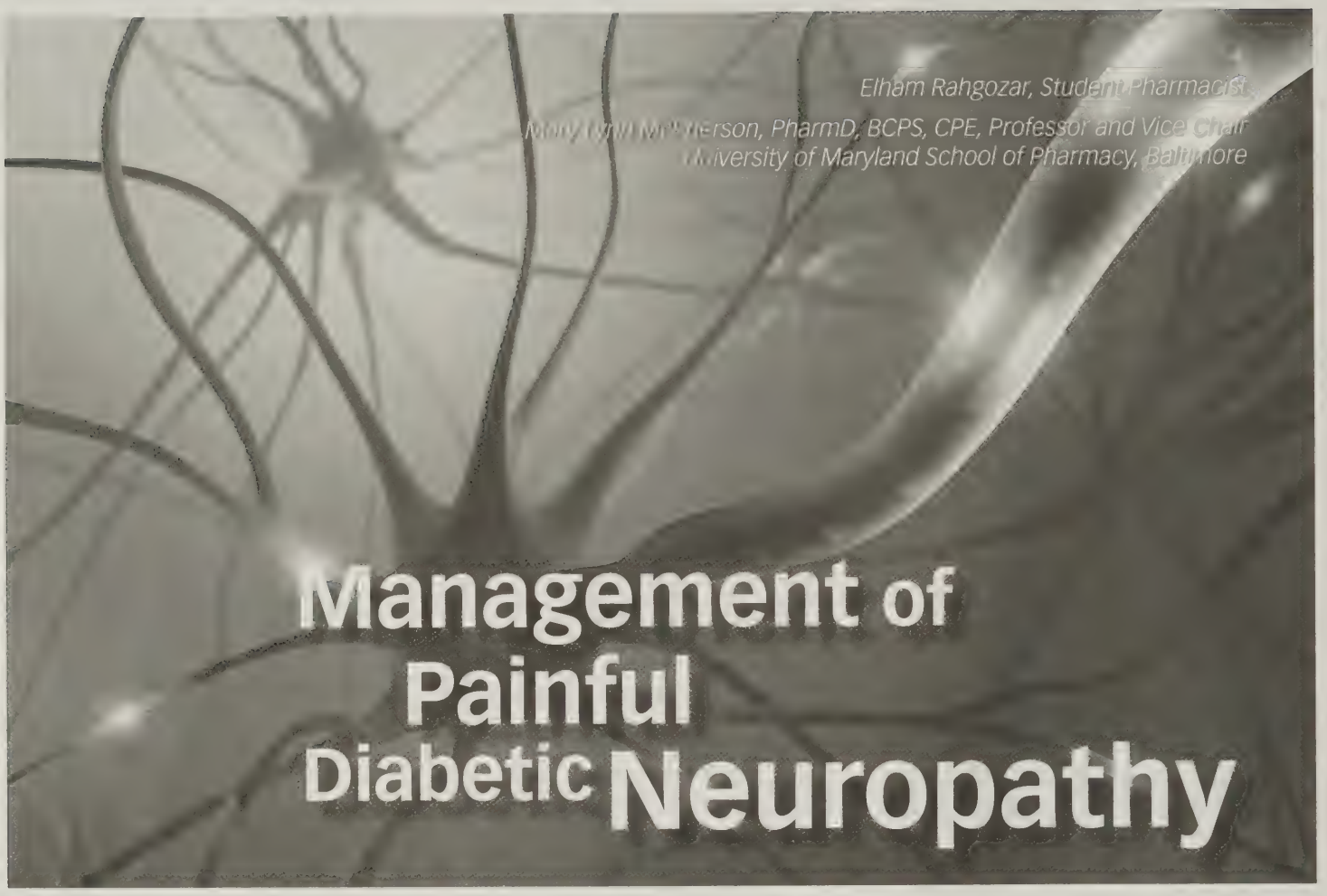

Elham Rahgozar, Student Pharmacist
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Management of Painful Diabetic Neuropathy

Mr. Smith approaches the counter in your community pharmacy and asks "My feet are freezing cold at night. I was thinking this heating pad might be helpful. What do you think?" You pull Mr. Smith's medication profile and find he is taking the following medications:

- HCTZ 25 mg by mouth daily
- Simvastatin 40 mg by mouth daily
- Lisinopril 20 mg by mouth daily
- Metformin 1000 mg by mouth twice daily
- Januvia 100 mg by mouth daily
- Metoprolol XL 50 mg by mouth daily
- MVI one by mouth daily

You see that he has a history of hypertension, hypercholesterolemia, and type 2 diabetes mellitus. You ask him if he has mentioned the cold feet to his physician and he responds "Oh yes, he said it was due to the diabetes. Something about nerve damage. I didn't quite understand what he was getting over."

Mr. Smith most likely has diabetic peripheral neuropathy (DPN), a chronic complication often associated with diabetes mellitus. Diabetic neuropathy is a type of nerve damage resulting from chronic hyperglycemia, affecting up to 50% of patients with long term diabetes, although not all experience pain or pain of an intensity that requires treatment.[1] These injured nerves will discharge spontaneously in response to both painful and non-painful stimuli. As a result, the patient may be prone to allodynia (pain from a non-painful stimulus such as touch) and hyperalgesia (increased sensitivity to pain). This may manifest as numbness, tingling, or pain in the toes, feet, legs, hands, arms, and fingers. Neurologically, the longest nerve axons are affected first, hence, a "stocking-glove" distribution is seen with pain and abnormal sensations starting in the toes and expanding up the legs and into the hands.[2]

Learning objectives

After reading this article, you will be able to:

- Describe the pathophysiology and clinical presentation of painful diabetic neuropathy.
- List evidence-based treatment options for the management of painful diabetic neuropathy.
- Describe the dosing strategy for a pharmacotherapeutic regimen used to treat painful diabetic neuropathy, including an initial dose and dose range.

Key Words

Pain management
Painful diabetic neuropathy
Tricyclic antidepressants (TCA)
Gabapentinoids
Serotonin-norepinephrine reuptake inhibitors (SNRI)

The assessment of DPN includes a thorough history and peripheral neurologic and vascular examination. Comorbid neurologic and vascular abnormalities associated with DPN put the patient at risk for poor wound healing, infections, and in severe cases, amputations of the toes, foot or leg. When DPN causes pain, patients may describe the sensation as burning, stabbing, shooting pain, or an electric shock.[2] Painful diabetic neuropathy specifically refers to pain as described in the extremities; diabetic neuropathy is a more global description that can result in urinary tract problems, digestive system abnormalities, blood vessel disease and heart failure.[3]

Painful diabetic neuropathy is a chronic condition with no effective treatment. Research has clearly demonstrated that enhanced glucose control significantly reduces the risk of developing clinical neuropathy, reducing nerve conduction and vibration threshold abnormalities.[4] Additionally, the progression of the disease may be delayed with improved glycemic control and patient education.[4-5] The Oslo study investigated the long-term (8 years) effects of glycemic control and concluded that each 1% rise in A1C level slows down nerve conduction by 1.3 m/sec.[6] Importantly, however, stricter blood glucose control has been shown to increase the risk of severe hypoglycemic episodes.[4] As a result, it is evident that glycemic control plays an important role in management of diabetic peripheral neuropathy and should be considered in all diabetic patients for both the prevention and management of neuropathy.

The management of painful diabetic neuropathy is primarily symptomatic. Traditional analgesics such as acetaminophen or nonsteroidal anti-inflammatory drugs are not effective in the management of neuropathic pain, including painful diabetic neuropathy. The Neuropathic Pain Special Interest Group of the International Association for the Study of Pain recently published guidelines for the treatment of neuropathic pain of all types.[7] They acknowledge in these guidelines that most randomized clinical trials evaluating the management of neuropathic pain primarily show partial relief in no more than half of patients. Additionally, the development of adverse effects is fairly common, and patients frequently are unable to tolerate treatment. Despite these limitations, this group developed recommendations for first-, second-, and third-line medications for the management of neuropathic pain. First-line recommendations include tricyclic antidepressants (TCAs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), calcium channel $\alpha_2\delta$ ligands (gabapentin and pregabalin), and topical lidocaine. Second-line medications include tramadol and opioid analgesics. There are a variety of third-line medications that include other antidepressants and anticonvulsants, capsaicin, dextromethorphan, memantine and mexiletine.[7]

The American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation published "Evidence-based guideline: Treatment of painful diabetic neuropathy."[8] They rated published clinical trials based on outcome measures. Their only Level A recommendation was pregabalin 300-600 mg/day. Level B recommendations were as follows:

- Gabapentin 900-3,600 mg/day
- Sodium valproate 500-1,200 mg/day
- Venlafaxine 75-225 mg/day
- Duloxetine 60-120 mg/day
- Amitriptyline 25-100 mg/day
- Dextromethorphan 400 mg/day
- Morphine sulfate, titrated to 120 mg/day
- Tramadol 210 mg/day
- Oxycodone mean dose 37 mg/day, maximum 120 mg/day
- Capsaicin 0.075% four times daily
- Isosorbide dinitrate spray
- Electrical stimulation, percutaneous nerve stimulation for 3-4 weeks

Interventions that were not recommended included oxcarbazepine, lamotrigine, lacosamide, clonidine, pentoxyfylline, mexiletine, magnetic field treatment, low-intensity laser therapy and Reiki therapy.[8] Let's take a closer look at the more common Level A and B recommendations. Dosing of commonly used agents is shown in Table 1.

Calcium Channel $\alpha_2\delta$ Ligands (gabapentin and pregabalin) – Pregabalin and gabapentin bind to voltage-gated calcium channels at the $\alpha_2\delta$ ligand, inhibiting neurotransmitter release. Pregabalin was shown to have a larger clinical dose-related effect than gabapentin in clinical trials of painful diabetic neuropathy, as well as enhancing quality of life.[8] Pregabalin and gabapentin have few drug interactions, but both cause dose-dependent sedation and dizziness; therefore, doses should be started low and titrated carefully.

Tricyclic Antidepressants (TCA) – TCAs block the reuptake of norepinephrine and serotonin, increasing levels of these neurotransmitters in the synapse and promoting neuronal activity. The strongest efficacy data for treating painful diabetic neuropathy is seen with amitriptyline; evidence is weaker with desipramine, imipramine and nortriptyline.[8] TCAs frequently cause sedation, orthostatic hypotension and anticholinergic adverse effects (dry mouth, constipation, urinary retention, blurred vision, cognitive impairment).[7] Doses are started low (10-25 mg at bedtime) and titrated slowly. Caution should be used with patients with a history of ischemic cardiac disease or ventricular conduction abnormalities.[7]

Selective Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs) – Duloxetine and venlafaxine have both been shown to be effective in treating the pain of diabetic peripheral neuropathy.[8] Since both agents are approved for depression, either of these agents are a reasonable choice when a patient has both depression and painful diabetic neuropathy. Doses should be started low and titrated carefully to

Table 1 • Comparison of first line therapies in the management of painful diabetic neuropathy

CLASS	MEDICATION	DOSE	COMMON SIDE EFFECTS	PRECAUTION	COMMENTS
TCA	Amitriptyline (Elavil, generic)	SD: 10-25 mg HS MDD: 150 mg (usually does not exceed 100 mg)	Dry mouth, constipation, weight gain, somnolence, dizziness, urinary retention, blurred vision. arrhythmias, heart block, QT prolongation.	Start low, titrate slowly. Serotonin syndrome.	Amitriptyline has more anticholinergic side effects.
	Nortriptyline (Pamelor, generic)	SD: 10-25 mg HS MDD: 150 mg (usually does not exceed 100 mg)			
SNRI	Duloxetine (Cymbalta)	SD: 30 mg (15 mg BID) MDD: 120 mg (60 mg BID; little benefit seen with doses above 60 mg per day)	Nausea, drowsiness, dizziness, dry mouth, constipation, blurred vision, anorexia, nervousness, insomnia, sweating, yawning.	Abrupt discontinuation should be avoided, suicidal thoughts, bipolar disorder, hepatic and renal impairment. Serotonin syndrome.	BBW: Patients should be monitored for worsening and emergence of suicidal thoughts and behaviors.
	Venlafaxine (Effexor, generic)	SD: 37.5-70 mg (37.5 QD- BID) MDD: 225 mg (75 mg TID)			
$\alpha_2\delta$	Pregabalin	SD: 150 mg (50 mg TID or 75 mg BID) MDD: 300 mg	Peripheral edema, dizziness, somnolence, difficulty concentrating, blurred/double vision, dry mouth, weight gain, loss of coordination.	Abrupt discontinuation, renal impairment, peripheral edema/CHF, suicidal behaior or ideation.	Cases of Stevens-Johnson syndrome have been reported with gabapentin.
	Gabapentin	SD: 100-300 mg HS or TID MDD: 1800 mg (600 mg TID)			
Opioids	Tramadol	SD: 25-50 mg four times daily MDD: 400 mg	Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, confusion.	Renal and hepatic impairment, seizures, do not use with suicidal ideation. Caution with history of drug abuse/ habituation.	Serotonin syndrome.
	Oxycodone	SD: 2.5-5 mg po q4h MDD: Should be individualized			Consider long-acting formulation after optimal total daily dose achieved.

SD: starting dose • MDD: maximum daily dose • HS: bed time • QD: one daily • BID: twice a day • TID: three times a day • BBW: black box warning

avoid adverse effects such as nausea with duloxetine. Venlafaxine can cause cardiac conduction abnormalities and hypertension, and therefore should be used with caution in patients with a cardiac history. It is important that patients remain adherent to therapy, particularly with venlafaxine, which can cause withdrawal symptoms with missed doses or sudden cessation of therapy.[7]

Opioids – Opioids such as morphine, oxycodone and tramadol are considered second-line in general for the management of neuropathic pain, and considered Level B options by the AAN guidelines.[7,8] The IASP guidelines acknowledge that opioids may be considered a first-line option when more rapid pain relief is needed, or while titrating an alternate agent to achieve the target dose.[7] Of course practitioners must be mindful of the risks of opioid therapy, and patients should be screened for potential drug abuse or misuse.

Combination Pharmacotherapy – In order to maximize therapeutic outcomes and minimize drug-induced adverse effects of drugs used in management of neuropathic pain, it may be worth considering rational polypharmacotherapy. Combination of two or more drugs with different mechanisms of actions at lower doses has been proven to be an effective strategy. For instance, lower doses of pregabalin could be combined with nortriptyline to control the pain more effectively while reducing side effects. These two coanalgesics act by different mechanisms of action which can enhance therapeutic outcomes, while causing fewer dose-related adverse effects. In a randomized controlled trial the combination of nortriptyline and gabapentin was shown to be superior when compared to the effects of either medication administered alone in a higher dose.[9] Although polypharmacy is traditionally discouraged, in pain management this strategy could result in added benefits and lower adverse effects when dosed and monitoring carefully.[10]

In summary, the best management strategy to prevent or slow the progression of painful diabetic neuropathy is improved blood glucose control for patients with diabetes, while using caution to avoid hypoglycemia. Patients with diabetes should receive comprehensive counseling about skin and foot care, the selection of footware, and daily inspection of hyposensitive areas and pressure points of the feet. Non-pharmacologic interventions are an important part of chronic pain management, possibly including percutaneous electrical nerve stimulation. Pharmacologic interventions generally include selected antidepressants, anticonvulsants or other agents, alone or in rational combinations.

Pharmacists have an important role to play in the education of patients about the use of these coanalgesics to treat pain, including explaining that they are not being used to treat depression or epilepsy respectively, but have been shown to have analgesic properties. Another important counseling point is that when antidepressants and anticonvulsants are used to treat neuropathic pain adherence to therapy is important; these are not "prn" medications to be used only when the patient experiences pain.

DR is a 54 year old morbidly obese woman who has a history of type 2 diabetes, osteoarthritis, chronic kidney disease, and chronic constipation. She presents for her quarterly visit with her primary care provider.

CC/HPI

DR's only complaint today is "this jabbing pain in my feet that has been getting worse over the past few months."

She describes her pain as numbness and pain in the distal aspect of the calves and feet, which she says is much worse at night when she tries to sleep. She scores her pain as a 5 during the day, 9 at night. She describes the pain as though her feet were "freezing cold like walking barefooted in the snow, with someone jabbing pins and needles into me." At times she recalls feeling electrical shocks and tingling. She had previously been active in her church (delivering meals for homebound patients) and gardening. She states her feet hurt so badly when she stands or walks that she cannot participate in these activities any longer.

She had tried acetaminophen to control her osteoarthritis (of both knees) pain. She had increased the acetaminophen to 1000 mg q4h to try to treat the pain in her feet/calves but she did not achieve any pain relief, and her community pharmacist advised her to reduce her acetaminophen total daily dose to 4 grams or less. She tried a friend's over-the-counter naproxen for the foot/calf pain but it upset her stomach. She also tried a friend's diclofenac topical cream but stopped using the cream because it didn't help her foot pain.

The patient describes feeling very unhappy about this pain, as well as having difficulty sleeping. She told her physician she was very distressed by her lot in life, and he suggested she start a walking program because "exercise improves everything." She denies any history of mental illness or substance abuse but is concerned about using "narcotics" to control her pain because of media reports about people abusing these medications and the risk she might have of becoming addicted to them.

PMH

Patient has a history of osteoarthritis for about 10 years, affecting both knees, right more than left. Pain present constantly, worse with weather changes, after sitting for more than 20-30 minutes, and when ascending stairs. She rates this pain as an average of 5 (on a 0-10 scale), best of 3 and worst of 7.

Diagnosed with type 2 diabetes about 15 years ago. Her diabetes is treated with recommended diet and exercise (she doesn't follow lifestyle modification recommendations; patient states she is "addicted to carbohydrates" and exercise hurts her knees) and glipizide.

History of chronic kidney disease for 3 years.

She complains of difficulty having bowel movements. She would like to achieve a bowel movement daily, but it's more commonly 3-4 times a week and she has to exert considerable straining.

CURRENT MEDICATIONS

Glipizide 10 mg po bid

Acarbose 50 mg po three times daily (patient does not take this medication due to abdominal pain and gas production)

Acetaminophen 1000 mg by mouth every 6 hours

Calcium + D one tablet per day

ALLERGIES/PREVIOUS ADR'S

No known allergies to medications

VACCINES

Up to date with childhood vaccinations; current with flu vaccine and Zostavax

Health maintenance: up to date with pap smear and performs monthly breast examinations

SOCIAL HISTORY

Smoking: Quit about 4 years ago

Alcohol: denies, except for one cocktail around the holidays

Illicit drug use: Denies

ROS

GU – history of chronic kidney disease; denies painful urination, nocturia, urinary retention or increase in urinary frequency

GI – difficulty having bowel movements as described in HPI. Denies diarrhea, rectal pain or bleeding.

Endocrine – denies appetite changes, cold intolerance, polyuria, polydipsia, polyphagia

Neuropsych – Positive for anhedonia, depressed mood, reduced sleep, decreased energy. Negative for suicidal thoughts, feelings of guilt or worthlessness

PHYSICAL EXAM

Ht/Wt: 5'4", 285 pounds

Vital signs: BP 140/84 mmHg, HR 88 bpm, RR 16, T 98.6

General: Well-developed, morbidly obese

Ext/Neuro: Abnormalities of the peripheral nervous system, skin and vascular supply for her distal lower extremities observed. Skin of her feet is shiny and thin, with a bluish coloration, and feet are cool to the touch. Pulses in feet are bilaterally diminished but symmetrical. Lower extremity strength testing is 5/5. Deep tendon reflexes are diminished at the ankles (1/4) relative to the knees (2/4) bilaterally. Sharp, thermal, and vibration sensations are absent from midcalves distally, and placement of the cool tuning fork directly against her feet caused an increase in her pain level. She has difficulty heel walking. Bilateral pitting edema (1+).

Neuropsych: Scored 16 on a Beck Depression Inventory-II

LABORATORY DATA

A1c 9.6 (8.8 six months ago)

Sodium 140, Potassium 4.2, Chloride 100, carbon dioxide 25, serum creatinine 1.4, BUN 28, glucose (random) 224

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What is the diagnosis of DR's problem?

DR most likely has moderately-severe painful diabetic neuropathy.

What is the therapeutic objective to treat DR's problem?

To relieve the pain to a level she finds acceptable, to allow DR to perform her desired activities of daily living (church activities, gardening, be able to sleep, relieve feelings of irritability and depression), prevent disease progression and prevent complications of diabetic neuropathy.

What patient- and drug-related variables should you consider before making a recommendation for DR?

Patient-related considerations include history of renal impairment (serum creatinine 1.4 mg/dl; creatinine clearance approximately 35 ml/min), health beliefs (doesn't want an opioid), history of diabetes and history of edema.

Agent-related considerations include need to dose adjust based on renal function (e.g., pregabalin, gabapentin), valproic acid worsens blood glucose, pregabalin is rated Level A, venlafaxine and duloxetine also treat depression.

What do you recommend to treat DR's complaint?

Duloxetine (Cymbalta) 30 mg by mouth once daily. After one week increase to 60 mg by mouth once daily (provided patient is nausea-free). Hopefully this will help with the painful diabetic neuropathy, and her depression. If a second analgesic is needed, consider adding pregabalin or gabapentin.

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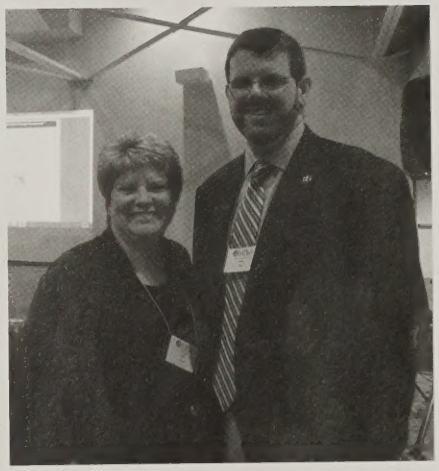

Photo 1 – Featured Stacie Maass kicked off the Summit with her update on Provider Status

Photo 2 – Andrew Haines, Chris Charles, and MPhA Speaker of the House Chai Wang

Photo 3 –Vice President Dixie Leikach with Chairman of the Board Brian Hose

Photo 4 – Professional Committee Co-Chair Hoai-An Truong and Matthew Balish

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